DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 101, and 115

[Docket Nos. 98N–1230, 96P–0418, and 97P–0197]

RIN 0910–AB30

Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising its food labeling regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy *Salmonella* microorganisms. The agency also is requiring that, when held at retail establishments, shell eggs be stored and displayed under refrigeration at a temperature of 7.2 °C (45 °F) or less. FDA is taking these actions because of the number of outbreaks of foodborne illnesses and deaths caused by *Salmonella* Enteritidis (SE) that are associated with the consumption of shell eggs. These actions also respond, in part, to petitions from Rose Acres Farm, Inc., and the Center for Science in the Public Interest (CSPI). Safe handling statements will help consumers take measures to protect themselves from illness or deaths associated with consumption of shell eggs that have not been treated to destroy *Salmonella* (all serotypes). Refrigeration of shell eggs that have not been treated to destroy *Salmonella* will help prevent the growth of SE in shell eggs.

DATES: This rule is effective [*insert date 270 days after date of publication in the* **Federal Register**], except § 115.50, which is effective [*insert date 180 days after date of publication in the* **Federal Register**].

NFR 1

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SUPPLEMENTARY INFORMATION:

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I. Background

FDA and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) share Federal authority to regulate eggs. The two agencies published in the **Federal Register** of May 19, 1998 (63 FR 27502), an advanced notice of proposed rulemaking seeking information on how to identify farm-to-table actions that would decrease food safety risks associated with shell eggs. On July 1, 1999, FDA and FSIS, in testimony before the Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia of the Senate Committee on Governmental Affairs, committed to developing by November 1, 1999, an action plan to address the presence of SE in shell eggs using a farm-to-table approach. On August 26, 1999, FDA and FSIS jointly held a public meeting to gather stakeholders' input and to discuss the development of the action plan. On December 10, 1999, FDA and FSIS presented the Egg Safety Action Plan (Ref. 1) to the President. The plan identifies the systems and practices from production to consumption that must be implemented to reduce and, ultimately, eliminate eggs as a source of human SE illnesses. This plan includes requirements for refrigeration at retail and requirements for the safe handling statement being issued in this rulemaking. FDA, along with FSIS, intends to use information gathered by both agencies to develop and implement a comprehensive program to address the safety of shell eggs from farm to table.

In the **Federal Register** of July 6, 1999 (64 FR 36492), FDA published a proposed rule (hereinafter referred to as ''the proposal'') to require safe handling label statements on shell eggs that have not been treated to destroy *Salmonella* microorganisms and refrigeration of these shell eggs while held by retail establishments. In a separate document in the same issue of the **Federal Register** (64 FR 36516), FDA published a Preliminary Regulatory Impact Analysis (PRIA) and Initial Regulatory Flexibility Analysis of the proposal. FDA proposed these regulations because of the number of outbreaks and deaths associated with the consumption of shell eggs that have not been treated to destroy *Salmonella*. Interested parties were given until September 20, 1999, to comment on the proposal.

FDA received approximately 790 responses, each containing one or more comments, to the proposal. These responses were received from the egg industry, egg packaging companies, trade associations, consumers, consumer interest groups, animal interest groups, academia, State Government agencies, members of Congress, and a foreign Government agency. More than 700 of these comments addressed forced molting, which is directed at the production of shell eggs, and, therefore, outside of the scope of this rulemaking, and will not be addressed in this document. Other comments also addressed issues that are outside the scope of this rule and will not be addressed in this document (e.g., implementation of national standards for quality assurance (QA) programs, implementation of Hazard Analysis and Critical Control Points (HACCP) programs, use of sanitary standard operating procedures, Good Agricultural Practices/Good Manufacturing Practices, and other intervention procedures such as manipulation of feeds and competitive exclusion to control SE, sell-by dates, uniform coding, repacking of shell eggs, refrigeration of nest run shell eggs, and creation of a single food safety agency responsible for eggs). These comments were considered by the agency in its action plan to address the presence of SE in shell eggs and will be considered in the development of subsequent proposed measures aimed at improving egg safety.

Some of the remaining comments supported the proposal. Others opposed the proposal or suggested modifications to the proposal. The relevant comments and the agency's responses to the comments are discussed below.

II. Shell Egg Labeling

A. Rationale for the Safe Handling Statement

In the proposal, FDA discussed the risk of foodborne illness associated with the consumption of shell eggs. In 1997, there were 7,924 SE isolates reported to the Centers for Disease Control and Prevention (CDC). In 1998, 58 percent of the SE outbreaks reported to CDC where a food vehicle was identified implicated foods containing eggs. Although recent CDC data show a 44

percent decrease in the isolation rate of SE, FDA believes that the incidence of SE is still too high. As discussed in the proposal (64 FR 36492 at 36501), FDA believes that it could take considerable time to design and implement a complete program that would eliminate eggs as a source of human SE illnesses, and indeed the Egg Safety Action Plan has a 10-year timeframe to achieve that goal (Ref. 1). However, as part of this program, FDA determined that there are measures that can be put in place quickly that can reduce the risks to consumers: refrigeration, which lengthens the effectiveness of the eggs' natural defenses against SE and slows the growth rate of SE, and thorough cooking, which kills viable SE that may be present. The agency maintained in the proposal that, unless informed about the risks presented by eggs contaminated with SE and ways that they may reduce these risks, consumers could suffer serious illness or death from consumption of raw or undercooked eggs. Accordingly, FDA proposed to require safe handling statements on shell eggs to inform consumers that there may be a risk associated with consumption of eggs and ways that they can properly handle and prepare eggs in order to reduce such risks.

(Comment 1) Several comments maintained that FDA overstated the magnitude of the risk associated with SE. One comment contended that the incidence of illness cited in the proposal was misleading. For example, the comment stated that information on all cases of salmonellosis was cited with the implication that it has a direct application to salmonellosis from SE. The comment stated that information on foodborne disease data from the years where salmonellosis associated with SE was increasing were included in the proposal, whereas, data from 1995 to 1998 showing a decrease in salmonellosis associated with SE were omitted. Some comments pointed out that recent data from CDC showing a 44 percent decrease in the isolation rate of SE from 1996 to 1998 do not support FDA's conclusion of a continued predominance of SE. Furthermore, one comment pointed out that there was only a 14 percent decrease in the isolation rate of all *Salmonella* serotypes in the same time period as the 44 percent decrease in the isolation rate of SE.

FDA disagrees that it overstated the magnitude of the risk associated with SE. The comment misunderstood how the data were presented in the proposal. FDA did not present the data regarding the incidence of all cases of salmonellosis to imply that these cases were reflective of SE-associated cases of salmonellosis. Rather, FDA used this information to place SE-associated salmonellosis in context of the epidemiology of *Salmonella* overall. First, in the proposal, FDA discussed the severity of salmonellosis and the magnitude of the disease, i.e., numbers of reported illnesses. Next, the agency discussed the numbers of SE-associated cases of salmonellosis and the fact that shell eggs are the major source of SE-related cases of salmonellosis where a food vehicle is identified.

The agency also disagrees with the comment stating that FDA did not include information on the decrease in the rate of infections caused by SE from 1996 to 1998. On the contrary, in the proposal (64 FR 36492 at 36493), FDA stated that recent CDC data showed a 44 percent decrease in the isolation rate of SE. However, the agency concluded that, even with the decrease in the isolation rate of SE reported by CDC, the incidence of SE associated with eggs was still too high and additional measures could and should be put in place to reduce the incidence even further.

B. Safe Handling Statement

In the proposal, FDA tentatively concluded that certain elements were essential to an effective safe handling statement, i.e., an informational statement that describes the hazard and the at-risk consumers, an instructional statement that describes measures that consumers can take to reduce or eliminate the risk, and a linking statement that relates the informational statement to the instructional statement. Applying the essential elements, FDA crafted several examples of label statements. FDA conducted focus group research to evaluate consumer understanding of the safe handling statements to test their effectiveness in informing consumers of the risks associated with

shell eggs and of the safe handling practices that may be used to mitigate the risks.[1] Based on information from the focus groups, FDA proposed to require the following safe handling statement on shell eggs that have not been treated to destroy *Salmonella*:

SAFE HANDLING INSTRUCTIONS:

Eggs may contain harmful bacteria known to cause serious illness, especially in children, the elderly, and persons with weakened immune systems. For your protection: keep eggs refrigerated; cook eggs until yolks are firm; and cook foods containing eggs thoroughly.

1. Comments on the Focus Group Research

(Comment 2) Several comments questioned FDA's focus group research. One comment maintained that, although focus groups are helpful tools to obtain feedback on food safety messages, FDA tested four very similar versions of the same label statement and, therefore, could not judge whether its proposed statement provided consumers with information they thought was necessary. The comment concluded that the label statements tested by FDA did not adequately reflect how consumers perceived FDA's proposed safe handling statement versus any other statement.

FDA disagrees with this comment. The comment misunderstood the intent of the focus group research. The intent of the research was for FDA to gauge how best to word the safe handling statement so that it is understood by consumers, not to determine what information is necessary in the statement. FDA developed several statements containing information judged by FDA subject matter experts to be most necessary to consumers. These subject matter experts arrived at their

[1]The moderator of the focus groups asked participants about their knowledge of the possible health effects associated with eggs as well as their personal experiences with handling eggs. After assessing the participants' knowledge and attitudes, the moderator gave the participants a series of safe handling statements for shell eggs on individual sheets of 8.5 x 11-inch white paper. The moderator engaged the participants in discussions on the impact of the statements and asked them to compare each statement with the other statements. The moderator also asked participants to comment on the format of the statements. The focus of the discussions was whether they understood the message.

determination of necessary information content after considering suggestions for messages that were submitted by outside organizations (Ref. 2). FDA provided five different safe handling statements for discussion in the focus groups. During the focus groups, participants discussed specific phrasing or message elements within each statement to gauge the effect of both the specific elements of the message and the overall message. Participants also provided input on how formatting could make the statement more readable. Thus, while adhering to the content judged necessary by FDA subject matter experts, the agency assessed numerous variations in how to best word and format the statement to communicate effectively with consumers.

(Comment 3) One comment stated that, although FDA did conduct some focus group testing, it should conduct direct testing such as mall-intercept studies to further refine the statement. This comment maintained that considering the susceptibility of older persons to foodborne illness, FDA should direct its message testing to this group.

FDA disagrees that it needs to conduct mall-intercept studies to fine tune the statement. If focus group results are not clear cut, then an experimental quantitative method such as mall-intercept studies could be used to fine tune the message. In this case, however, the focus group results were so consistent that FDA did not deem it necessary to conduct experimental testing. In addition, the focus group testing of the safe handling statements included consumers 60 years of age and older. These older consumers did not differ greatly from younger consumers in their responses to the safe handling statements that were tested. Consequently, FDA sees no need to conduct additional testing on older persons.

2. Description of the Hazard

Most of the comments that responded to the proposed labeling supported the concept of safe handling instructions for shell eggs. However, some of these comments opposed the specific language in the proposed statement for the reasons discussed below.

(Comment 4) Many of these comments asserted that including a description of the hazard, i.e., ''eggs may contain harmful bacteria known to cause serious illness, especially in children, the elderly, and persons with weakened immune systems,'' is unwarranted.

Several comments contended that the hazard description will distract consumers from the safe handling instructions. To support this assertion, one comment presented consumer research from the American Egg Board (AEB) and concluded from it that most respondents saw FDA's proposed label statement as a warning that eggs are harmful rather than a message to promote safe handling. Some comments asserted that consumers have become weary of labels and warnings and no longer pay attention to them. Other comments expressed their concern that, because of the length of the hazard description, consumers may not read the entire statement and, thus, would not read the safe handling instructions.

Several comments that opposed the inclusion of the hazard statement maintained that consumers are aware of risks associated with SE in eggs and, therefore, the description is unnecessary. One of these comments presented data from a survey conducted by the California Department of Public Health Services that showed that 84 percent of the respondents were aware that eggs contained bacteria that could cause illness. The comment also pointed out that a consumer survey in Iowa reported that 93 percent of those surveyed were aware of *Salmonella* in eggs. Another survey in California showed that 86 percent of the English-language respondents were aware of *Salmonella* in eggs. The comment noted that a FDA survey in 1998 showed that ⅔ of respondents had heard of *Salmonella* and knew that cooking would kill it. This represented a 60 percent increase from a survey done in 1993. According to another comment, before FDA implements such a strongly worded safe handling instruction, it should determine whether consumers are really uninformed about the possibility of the presence of illness-causing bacteria in eggs.

Several comments maintained that the proposed safe handling statement for eggs is more harsh than the safe handling statement on meat and poultry and, therefore, unfairly targets the egg

industry. One comment pointed out that USDA's risk assessment estimated that the contamination rate for eggs is 1 egg in 20,000, which, according to the comment, is several orders of magnitude lower than most animal products. Thus, the comment maintained that because the risk of becoming ill can be eliminated completely with proper handling and cooking, such a harsh hazard description for a product with a small risk is not justified.

In the proposal, FDA discussed its concern that unless consumers are advised of the risks presented by eggs contaminated with SE and ways that they could reduce these risks, consumers, especially those that are at greatest risk, could suffer serious illness or death from the consumption of raw or undercooked eggs. The agency's primary intent in proposing the label statement for eggs was to give consumers ways to reduce their risk, without having to avoid the product. In addition, consumer research available to the agency indicated that label messages generally are more credible when consumers know the reason for the message (Ref. 3). Therefore, the agency tentatively concluded that to adequately inform consumers there was a need to include information on why there was a risk associated with consumption of raw or improperly cooked shell eggs. However, in light of the comments that asserted that the hazard description: (1) Is not new information, (2) is not consistent with safe handling statements on other raw animal products, and (3) may distract consumers from the safe handling instructions, the agency is persuaded that it should reconsider the necessity of the hazard description as proposed.

The agency is persuaded by information provided by FDA's consumer research and comments to the proposal that the risks associated with consumption of SE-contaminated eggs is not new information to consumers. FDA survey data indicate that the percentage of consumers eating raw eggs has declined in recent years, as appropriate food safety practices have received more publicity (Ref. 4). FDA's own focus group research indicated that many consumers were aware that *Salmonella* is the major cause of foodborne illness associated with egg consumption. Because many of the consumers stated that they knew of the risk associated with eggs, they considered the safe handling statement to be more of a reminder than to provide new information.

FDA recognizes that the proposed label statement is different than that for meat and poultry. In crafting the label statement, the agency relied on previous focus group research that indicates consumers prefer messages that are more specific to the nature of the hazard and the appropriate action to take because of the hazard (Ref. 3). The agency points out, however, that there are differences in the labeling issues involved, which result in some differences in wording. For example, in the meat/poultry safe handling statement there is no specific mention of the food, rather the statement uses ''some products'' whereas, the proposed statement for eggs refers to ''eggs.'' The agency points out that the meat/poultry statement was designed to appear on a very wide range of products, therefore, it needed to be more general in the way that it identifies foods. The egg label statement will appear only on eggs and, therefore, can be more specific. However, FDA acknowledges that the proposed hazard description on the labels of eggs may appear more harsh than the hazard description on the packages of meat/poultry. The agency does not want consumers to be confused about the level of risk associated with the consumption of raw or undercooked eggs versus consumption of any other raw or undercooked animal product.

FDA has decided to revise the safe handling statement by removing the proposed hazard description, i.e., ''eggs may contain harmful bacteria known to cause serious illness especially in children, the elderly, and persons with weakened immune systems'' and replace it with a shorter hazard description. FDA continues to believe that the safe handling statement would be more effective if consumers knew that the reason for following the safe handling instructions was to prevent illness from bacteria. Consequently, FDA has decided to minimize the potential for misunderstanding by shortening the introductory hazard description to ''to prevent illness from bacteria.'' As was the case with the proposed hazard statement, this statement alerts consumers to the reason why it is important to adhere to the safe handling instructions and does not have the same potential as the proposed statement to distract consumers from the safe handling message.

Accordingly, based on the findings of the agency's consumer focus group research and comments to the proposal, FDA is revising the safe handling statement in proposed § 101.17(h)(1) to read as follows:

SAFE HANDLING INSTRUCTIONS:

To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.

3. Description of At-Risk Consumers

(Comment 5) A few comments opposed the description of at-risk groups in the hazard statement. According to one comment, consumers would perceive that the safe handling instructions are targeted only at the groups listed in the statement. Another comment pointed out that the safe handling labels on meat and poultry do not list at-risk groups. This comment contended that because of the low probability of contamination of eggs, vulnerable populations are no more at risk from eggs, and probably at less risk, than they are from any other raw animal product. One comment requested removal of the at-risk groups from the proposed safe handling statement because the reference to at-risk groups may heighten the misperception that eggs are a dangerous food.

FDA points out that the new hazard description does not include the listing of at-risk consumers. While FDA survey data indicated that most consumers do not know that some people are at a higher risk of foodborne illness than others and that focus group participants thought that the information on at-risk groups was an important aspect of communicating the nature of the hazard, the agency has reconsidered whether, in this case, it is necessary to provide that information on the labels of eggs. The agency acknowledges that the labels of meat/poultry do not include the listing of at-risk consumers. Because vulnerable populations are at greater risk of most foodborne illnesses, FDA believes that it would be better to provide this information to these consumers through educational channels rather than to tie the information to specific products. FDA does not want at-risk populations to be misled to believe that eggs present a greater risk to them than other raw animal products. Thus, the agency decided to remove the at-risk consumers

from the proposed safe handling statement on eggs to be consistent with label statements on other raw animal products.

FDA believes that the information that eggs may be harmful to certain vulnerable populations is important information that must be conveyed to these consumers. Therefore, FDA will continue to provide information about food safety to consumers, including those at greater risk. In addition, FDA plans to develop an educational and outreach campaign after the publication of this final rule to bring attention to the new requirements for shell eggs and to disseminate information to consumers, particularly at-risk populations and those that prepare their meals.

4. Cooking Instructions

(Comment 6) Most comments agreed that there should be an instruction on proper cooking. Although some of the comments supported the language in the cooking instruction, i.e., ''cook eggs until yolks are firm, and cook foods containing eggs thoroughly,'' a few comments objected to the cooking instruction. One comment stated that the phrase ''cook thoroughly'' may be too vague, but offered no alternative language. Another comment contended that FDA should eliminate the phrase ''cook foods containing eggs thoroughly'' because it is impossible to cook some egg-containing foods thoroughly, e.g., meringue and Caesar salad. The comment asserted that these foods can be made safe by using pasteurized eggs or avoiding the food. Therefore, the comment concluded that because the proposed phrase cannot be followed in all cases, it should be removed.

FDA disagrees with the elimination of the phrase ''cook foods containing eggs thoroughly.'' FDA believes that it is necessary to inform consumers that, when cooking or preparing a food that contains raw eggs, the food must be cooked thoroughly to reduce the risk of illness. The agency rejects the notion that the cooking instruction should be removed because it is not possible to cook all egg-containing foods thoroughly. The intent of the cooking instruction is to give consumers information generally on how to properly cook eggs and egg-containing foods to reduce risks. The intent of the message is not to cover every possible scenario as it relates to eggs. The agency concludes that if consumers recognize that they are at risk of illness if they consume a

food that is made with a raw or undercooked egg, they would avoid the food or use a substitute, e.g., pasteurized egg product, to reduce the risk. Thus, FDA is retaining the cooking instructions, as proposed, in the safe handling statement.

In the proposal, FDA requested comment on whether it should require a statement that the product should not be used for certain purposes, e.g., ''use pasteurized eggs for recipes requiring raw or partially cooked eggs.'' The agency also requested comment on whether it should include on the label an explicit instruction to avoid the product for at-risk consumers or for individuals preparing food for at-risk consumers.

(Comment 7) One comment stated that FDA should not use the phrase ''use pasteurized eggs for recipes requiring raw or partially cooked eggs'' because consumers cannot readily purchase certain pasteurized egg products in retail stores, e.g., egg whites. However, the comment did not provide data on the availability of the product. There were no comments that supported use of the statement ''use pasteurized eggs for recipes requiring raw or partially cooked eggs.''

Because there was no support for the subject statement, the agency is not requiring it in the safe handling statement. In addition, FDA did not receive any comments on whether it should include an explicit instruction for at-risk consumers to avoid the product, and therefore, is not requiring such a statement. However, as announced in the Egg Safety Action Plan, FDA plans to take additional steps to protect at-risk consumers by establishing safe egg handling and preparation practices consistent with provisions in the Food Code. (Refs. 1 and 5).

5. Other Comments on the Text of the Safe Handling Statement

(Comment 8) Some comments maintained that the description of the hazard will frighten consumers and will discourage consumers from eating eggs. According to one comment, eggs have a history of consumer avoidance because of the fear of heart disease from dietary cholesterol provided by eggs. This comment asserted that, given the history and perception that eggs are a dangerous food, the proposed statement may likely lead to further avoidance of eggs. The comment

suggested that additional language be placed on the carton to combat the negative connotation of the safe handling statement.

It is not the agency's intent to frighten consumers or discourage consumption of eggs. Rather, the main purpose of the proposed label statement is to provide consumers with information on how to prepare eggs safely. FDA focus group research did not indicate that the proposed hazard description frightened consumers. Rather, the research indicated that consumers perceived the hazard statement as a helpful reminder about why they should handle eggs safely. Thus, FDA is not persuaded that additional language to combat a negative connotation of the safe handling statement is warranted. Nevertheless, the agency believes that it is less likely that the revised safe handling statement would frighten consumers.

(Comment 9) A few comments asserted that the hazard description is unwarranted for eggs produced under a proven risk-reduction program. According to one of these comments, consumer perception of the frightening or negative nature of the message would negate the effort put forth by producers who use these food-safety programs. Another comment contended that the proposed label statement with the hazard description has the potential to increase foodborne illness because producers would be less likely to participate in risk reduction programs if their products would still be required to bear the hazard component of the safe handling statement. The comments suggested a two-tiered label system, i.e., one label statement for eggs produced under QA systems and another for eggs that are not produced under QA systems. Another comment that supported the two-tiered concept contended that although the safe handling statement on eggs produced under on-farm QA programs could have a less stringent hazard description, it should not omit the reference to the potential hazard. The comment offered the following two tiered labeling scheme:

For eggs not in QA programs:

Caution: Eggs may contain illness-causing bacteria. Keep refrigerated. Do not eat raw.

Cook until yolk is firm.

For those in QA programs:

SAFE HANDLING INSTRUCTIONS: To prevent illness, keep refrigerated. Do not eat raw. Cook until yolk is firm.

As an alternative to the proposed label statement, one comment suggested that FDA develop and adopt a ''positive'' label system that would recognize eggs produced under proven risk reduction programs.

FDA recognizes and applauds the work being done by States and industry to address egg safety. However, FDA believes that two different label statements in the marketplace may be confusing to consumers. A different safe handling statement for eggs produced under QA programs could mislead consumers to believe that those eggs do not require safe handling when, in fact, both categories of eggs should be handled safely. However, in light of the agency's decision to revise the hazard description to ''to prevent illness from bacteria,'' the question of a two tiered labeling scheme with a less stringent hazard description for eggs produced under QA plans becomes moot. Finally, the agency is not persuaded to develop a ''positive'' labeling scheme for eggs produced under QA plans, since like the two-tiered approach, it could create confusion. However, FDA would not object to ''positive'' statements, or any other voluntary information on the labels of eggs, as long as the information is truthful and not misleading. This information may not appear inside of the box with the required safe handling statement. FDA points out that information may be considered misleading, for example, if it implies that a food is safer than other similar products that may not be labeled.

(Comment 10) One comment from a foreign government stated that it uses QA programs and HACCP principles to ensure egg safety and that its eggs for export into the United States must be SE-free. Thus, the comment asserted that the proposed label statement is unnecessary for its products.

The agency does not agree with the comment that a foreign government requirement that eggs for export into the United States be SE-free negates the necessity for safe handling instructions. Unless eggs have been specifically treated to destroy *Salmonella*, FDA believes that

there still is a chance that the eggs contain transovarian-transmitted SE. Further, FDA notes that it regulates both domestic and imported foods on an equal basis. As discussed above in this section, FDA is not permitting a different safe handling statement for eggs produced under QA plans. Thus, FDA is not establishing different labeling criteria for imported eggs based on the requirements of the country of origin.

(Comment 11) A few comments stated that the safe handling statement should begin with the terms ''caution'' or ''notice.'' One of these comments stated that the word ''caution'' or ''notice'' would attract the consumer's attention. Another comment asserted that the serious public health threat posed by SE warrants a cautionary statement on labels that informs consumers that the way they are accustomed to eating eggs may no longer be safe. This comment contended that the term ''safe handling instructions'' does not achieve the objective of communicating to consumers quickly and unambiguously that eggs may be unsafe. Further, according to the comment, the word ''caution'' unlike ''warning'' or ''danger'' would not cause the consumer to avoid the product altogether.

Consumer research indicates that the word ''caution'' has the same connotation to consumers as ''warning'' and is, therefore, inappropriate for a safe handling statement (Ref. 6). Because FDA's focus group research indicates that consumers believe that there are practical, simple things they can do to control the risk from eggs, a safe handling statement is more appropriate and, consequently, the most appropriate signal words are ''safe handling instructions.'' In addition, as discussed in the proposal (64 FR 36492 at 36505), FDA considered the term ''notice'' to introduce the safe handling statement and concluded that the term would not draw attention to the important fact that there are ways to reduce the risks of foodborne illness other than avoidance of the product. Therefore, FDA is not changing the phrase ''safe handling instructions'' to ''caution'' or ''notice.''

(Comment 12) One comment expressed the concern that the safe handling statement would be difficult to understand because it is above a fifth grade reading level.

FDA points out that considerable effort was made to ensure that the language in the statement would be understandable to consumers. Specific phrases or message elements were tested for comprehensibility either in the egg focus groups or in previous consumer research on food safety issues. For example, results of the focus group research indicated that some participants were confused by the term ''shell eggs'' and found ''eggs'' more understandable. They also found the phrase ''cook eggs until yolks are firm'' more understandable than ''cook thoroughly.'' These findings were used to craft the proposed statement. Although focus group participants had varying educational levels, those with high level of education, e.g., graduate degrees, were excluded from participation. None of the participants appeared to find the message difficult to understand. Thus, the agency is not persuaded by the comment that the safe handling statement would be difficult to understand.

Other comments addressing the length of the safe handling statement and the specific wording of the hazard description in the safe handling statement have become moot because FDA has revised the statement. Therefore, those comments will not be addressed.

6. Alternatives to the Proposed Label Statement

(Comment 13) A few comments stated that the label statement on eggs for household consumers should be different from that on eggs for food service. One of the comments offered the following suggested labeling in a two tiered labeling scheme:

For household eggs:

Keep refrigerated and cook thoroughly

For eggs in food service:

Handle Safely: refrigerate promptly; don't cross contaminate; clean hands and surfaces often; cook to proper temperature.

FDA believes that the statement suggested by the comment for household consumers does not provide adequate information. For example, the statement required by § 101.17(h)(1) uses the phrase ''cook eggs until yolks are firm'' which is more descriptive than ''cook thoroughly.''

Furthermore, FDA was not persuaded by these comments that food service establishments need additional information on cartons of eggs. Although the agency recognizes that many of the SE-associated outbreaks occur in food service establishments, it does not agree that additional labeling is the best way to address this issue. Thus, the agency is not persuaded to change the safe handling statement to those suggested by the comment.

(Comment 14) One comment stated that a lengthy safe handling statement is unnecessary and, alternatively, supported the use of the following on shell eggs:

IMPORTANT: Must Be Kept Refrigerated to Maintain Safety

or

IMPORTANT: Must Be Kept Refrigerated

According to this comment, if FDA determines that the labels of shell eggs need safe handling instructions, then those instructions should be in addition to the statement above.

The agency is not persuaded that this suggested label statement is all that is needed on eggs to inform consumers of ways that they may protect themselves. As discussed in the proposal, two measures that would mitigate the risk of SE in shell eggs are refrigeration and proper cooking. The suggested message does not instruct consumers that proper cooking is a measure that they can take to protect themselves. The agency also rejects the comment's suggestion that the suggested statement appear on the label in addition to FDA's proposed safe handling instructions. Two statements on the label informing consumers to keep eggs refrigerated would be redundant. FDA believes that the phrase ''to prevent illness from bacteria'' informs consumers that refrigeration is one measure they can take to reduce or eliminate the risk of foodborne illness. Thus, FDA concludes that it is implicit in the safe handling statement that refrigeration helps maintain safety.

(Comment 15) A few comments preferred statements that were very short, clear, and aimed at all consumers such as ''do not eat raw or undercooked eggs'' and ''keep refrigerated, cook thoroughly, and do not eat raw'' with each of the instructions preceded by bullets. Other comments supported the following label statement that incorporates the basics of the Fight Bac campaign:

Safe Handling Instructions

CLEAN: Wash hands and surfaces often. SEPARATE: Don't cross contaminate

COOK: Cook to proper temperatures. CHILL: Refrigerate Promptly

This statement, according to one comment is a simple and positive message and was designed based on consumer focus research. Furthermore, the comment maintained that it does not single out a specific food item.

FDA is not persuaded to adopt the safe handling statements suggested by these comments. The agency believes that the suggested statements do not inform consumers why the safe handling instructions should be followed. Also, the agency notes that the statement incorporating the basics of the Fight Bac campaign educates consumers about food safety in general. However, FDA's proposal to require a safe handling instruction is being issued under 201(n) and 403(a) of the Federal Food, Drug, and Cosmetic (FD&C Act) (21 U.S.C. 321(n) and 343(a)). Under section 201(n) of the FD&C Act, in determining whether labeling is misleading, it must be taken into account, among other things, the extent to which labeling fails to reveal material information with respect to consequences that may result from the usual use of the product. FDA believes that, although instructions to wash hands and not to cross contaminate products are useful pieces of information, such information is not specific to eggs. Therefore, FDA is not persuaded to adopt this suggested alternative phrasing.

7. Placement and Prominence

a. *Placement and type size of the safe handling statement.* As discussed in the proposal, section 403(f) of the FD&C Act requires that mandatory label information be placed on the label with such conspicuousness as to render it likely to be read and understood by ordinary individuals under customary conditions of use. In the past, FDA has generally required label statements required by § 101.17 (21 CFR 101.17) to be placed on the information panel. The agency noted that the principal display panel (PDP) would provide even more prominence. Accordingly, the agency tentatively concluded to require the proposed safe handling statement either on the information

panel or the PDP. The agency also noted in the proposal that § 101.2(c) (21 CFR 101.2(c)) requires that mandatory information appearing on the PDP and information panel, including information required by § 101.17, appear prominently and conspicuously in type size no less than 1/16 inch. Consequently, the agency concluded that it was not necessary to repeat the requirements in this rulemaking.

(Comment 16) Some of the comments stated that there is not enough room on the egg carton to print such a lengthy safe handling statement with the other Federal and State mandated labeling requirements such as nutrition labeling, USDA grade and quality logos, product code, registration numbers to identify packers, date of pack, sell-by date, and count and weight. Some comments maintained that the lack of space is greater for small (six or eight count) cartons and pulp/open view cartons. Further, one comment pointed out that some of the manufacturers of smaller egg cartons are incapable of printing on the side of the lid. For those who have space to print on the side of the lid, the comment pointed out that the cost to purchase equipment needed to print on the side of the lid would cost several million dollars. Some comments asserted that the space on the label is used by some firms for promotional material, which is a critical selling feature for the firm. Therefore, according to these comments, further regulation would limit a firm's ability to market its own products. While one comment stated that the safe handling statement should be on the outside of the lid, other comments requested some flexibility for placement of the label statement. Two comments maintained that FDA should conduct more research to see if the statement should appear on the information panel and whether consumers would notice the statement there. One comment requested that for small cartons the safe handling information be communicated with an 800 telephone number printed on the carton, e.g., "FOR SAFE HANDLING INSTRUCTIONS, PLEASE CALL 1–(800)____–____."

FDA recognizes that manufacturers may have to redesign their labels, but believes that, in many instances and, particularly in light of the fact that the safe handling statement that will be required is about one-half the length of the one proposed, simply reducing the type size of non-

mandatory information will provide sufficient space to accommodate the safe handling statement in § 101.17(h)(1). Further, FDA believes that there is enough space on the foam type cartons of shell eggs (both the small, i.e., 6 to 8 egg carton, and larger cartons) to bear all other Federal and State mandated information as well as FDA's safe handling statement. In fact, some of those cartons now contain safe handling information that is comparable in length or more lengthy than FDA's revised safe handling statement. Therefore, for these cartons, FDA concludes that, as revised, there is ample space for its safe handling statement.

FDA also recognizes the limitation of label space on pulp style egg cartons. However, FDA believes that the pulp/open view cartons also have ample space for the shorter revised safe handling statement as evidenced by existing nonmandatory labeling. Thus, FDA is not revising the requirement in § 101.17(h)(2) that the safe handling statement must appear either on the PDP or the information panel of the label. The agency concludes that because there is ample space for the safe handling statement on both large and small cartons of shell eggs, FDA is not providing a telephone referral for the safe handling instructions for these cartons. In addition, FDA rejects the comments suggesting that it should conduct more research to determine whether consumers would notice safe handling instructions on the information panel. The comments did not provide any information that consumers would not notice the safe handling statement on the information panel and, therefore, FDA is not changing the provision of allowing the safe handling statement on the information panel.

(Comment 17) A few comments requested that FDA require a minimum type size. For example, one comment stated that 12-point type is best for older persons to read. The comment acknowledged that some egg cartons may not be able to accommodate 12-point type and stated that type size of less than 8-point would be difficult to read. One comment maintained that other formatting requirements would enhance the readability of the statement. For example, the comment suggested that FDA consider requirements for the use of simple type and use of ink and paper with sufficient contrast. Another comment suggested that FDA require that the statement appear

in a hairline box with adequate space around the statement and appear in dark words on light background to enhance the visibility.

FDA does not agree that it should require a minimum type size. The agency reiterates that § 101.2(c) requires that mandatory information appearing on the PDP and the information panel, including information in § 101.17, appear prominently and conspicuously in a type size of no less than 1/16 inch. Although comments recommended 12 point font for the safe handling statement to make it easier for older persons to read, one of these comments acknowledged that there may be insufficient space to accommodate the statement in that type size on the egg carton. Furthermore, the comments did not provide data to support the contention that older consumers are unable to read information on the information panel and PDP that appear in 1/16 type size. Accordingly, FDA is not requiring a minimum type size for the safe handling statement that is different from the minimum type size requirements in § 101.2(c). The agency also notes that 21 CFR 101.15 describes conditions that would make a label statement lack the prominence and conspicuousness required by § 101.2(c). Some of these include insufficient background contrast, and crowding with other written, printed, or graphic matter. Because these provisions are already in place for prominence and conspicuousness for information required by § 101.17, the agency finds that it is not necessary to repeat these requirements in this rulemaking.

b. *Use of graphics*. In the proposal, FDA recognized that safe handling instructions on meat and poultry utilized graphic illustrations. The agency tentatively concluded that its focus group research did not indicate that graphic illustrations were necessary to convey the safe handling instructions to consumers. However, the focus groups did respond favorably to bullets and the agency requested comment on whether graphics would enhance the visibility of the statement and whether it should require them.

(Comment 18) Some comments maintained that icons depicting actions to be taken (e.g., a refrigerator to indicate that product should be refrigerated) make the safe handling statement easier to understand. Other comments supported the use of bullets to enhance the safe handling statement.

One comment supported use of a graphic symbol to attract the consumer's attention to the label such as an exclamation point in a triangle. This symbol, the comment maintained, could become a universal symbol for foods that present a hazard.

The agency is not requiring these suggested labeling options. None of the comments provided data that showed that consumers would be better informed with graphics and, thus, did not call into question FDA's testing that showed that consumers would be adequately informed of safe handling information without the use of graphics. However, the agency would not object to the use of bullets or graphic illustrations in addition to what is required. Accordingly, graphic illustrations and bullets may appear with the safe handling statement to draw greater attention to the statement. However, other wording may not appear in the box with the prescribed label statement. As stated in the proposal (64 FR 36492 at 36504), FDA believes that prescribing the specific language of the safe handling statement gives manufacturers a level playing field by requiring the same language for all products covered by the regulation, while giving consumers a message that is not confusing, misleading, or ineffective.

c. *Labeling for shell eggs not for direct sale to consumers.* In the proposal, FDA stated that the safe handling statement on cartons of shell eggs that are not for direct sale to consumers, e.g., shell eggs that are to be repacked at a site other than originally processed or are to be shipped for use in food service establishments, would serve as a means to inform repackers and food preparers of the safe handling instructions. The agency tentatively concluded that the same goal of conveying the message could also be accomplished by customary practices of the trade. Thus, FDA proposed that the safe handling statement on shell eggs that are not for direct sale to consumers may be provided on cartons or in labeling, e.g., invoices or bills of lading in accordance with the practice of the trade.

(Comment 19) Some comments opposed labeling in invoices and bills of lading because, they asserted, the labeling may be separated from the product and not read by food handlers. The comments maintained that the safe handling instructions must be read and understood by the food

handler because they are the ones who must use the safe handling instructions when storing and preparing egg dishes. Moreover, according to one comment, the majority of eggs shipped to food service establishments are in 15 or 30 dozen cases that have ample room for labeling and, therefore, there is no need for the flexibility. One comment asserted that the proposed safe handling instructions should be on shipping containers and other food service packages because most incidents of SE-contamination in eggs occur in food service establishments.

The agency agrees that the safe handling instructions must be conveyed and understood by the food handler. However, the agency is not persuaded by comments that the safe handling statement would not reach the food preparers if it is not on the label. FDA believes that it is the responsibility of the owner/operator of the establishment to make sure that food preparers receive the safe handling instructions as well as training on how to implement the instructions. Moreover, the agency points out that it intends to ensure that food preparers receive safe handling information for shell eggs by establishing safe egg handling and preparation practices at retail consistent with the Food Code (Refs. 1 and 5). Thus, FDA is not persuaded to prohibit the use of labeling such as invoices and bills of lading as a means for meeting the requirements of this rule when the eggs are to be repacked, relabeled, or further processed.

8. Other Labeling Issues

(Comment 20) Some comments contended that the label statement will not significantly reduce the numbers of SE-associated illnesses.

The agency disagrees that the label statement will not significantly reduce the numbers of SE-associated illnesses. In the PRIA, FDA used a Food Marketing Institute study (Ref. 7) of the effects of USDA's meat and poultry safe handling instructions to estimate the effect of the safe handling label statement for shell eggs. The agency estimated that the likelihood that shell eggs would be undercooked or consumed raw would decline by approximately 5 percent. FDA also estimated that the likelihood that consumers would fail to refrigerate shell eggs would decline by 2 percent. These percentages continue to be the agency's best estimate of the approximate

effects of the safe handling label for shell eggs. In a separate simulation, FDA used its modification of USDA's SE risk assessment model[1] and CDC's surveillance model to estimate the effect of the safe handling label. With the FDA-modified SE risk assessment baseline, FDA estimated the number of illnesses that would be prevented by labeling to be 4,948 to 162,846 with a mean of 46,339. Using the CDC baseline, the estimate of the number of illnesses prevented by labeling was 2,813 to 42,892, with a mean of 14,775. As discussed below in section IV.A of this document, FDA used more recent data to adjust the CDC surveillance model used in the proposal. Thus, FDA's estimate of the number of illnesses prevented by labeling using the revised CDC baseline is 1,570 to 25,196 with a mean of 8,784. Comments did not provide FDA with other estimates of the prevention of salmonellosis. FDA maintains that its estimates represent a significant reduction in illness.

(Comment 21) Some comments contended that most outbreaks occur in food service establishments and, therefore, FDA's focus should be on educating and providing safe handling instructions for food service workers, not household consumers. On the other hand, one comment maintained that label statements are not going to change the behavior of food service workers who take shortcuts.

FDA disagrees with these comments. The agency believes that information about food safety should be given to both household consumers and food service workers. Previously in section

[1] The baseline for the cases of samonellosis was estimated in three different ways. The USDA risk assessment estimated the number of illnesses with a full farm-to-table model. The model included an estimate of the number of eggs infected, the number of infected eggs likely to be consumed, and an estimate of the number and severity of illnesses caused by SE. In the second model, FDA modified the USDA risk assessment model by using a 5 percent probability that shell eggs are refrigerated at 7.2 °C (45 °F) in retail establishments and institutions. FDA modified the original model based on more recent information on the numbers of establishments not refrigerating eggs at 7.2 °C (45 °F). The CDC model estimates the number of illnesses based on the number of confirmed cases as indicated by the number of SE isolates reported to CDC plus estimated unreported cases.

II.A of this document, FDA discussed its rationale for providing safe handling instructions for consumers. The agency recognizes that food service is an additional component of the farm-to-table continuum and points out that, as part of FDA's and FSIS' Egg Safety Action Plan, FDA intends to initiate rulemaking to establish safe handling and preparation practices for food service establishments based on sections of the Food Code related to egg safety (Refs. 1 and 5). FDA also points out that the requirement for refrigeration of eggs at retail, including food service establishments (see discussion below in section III of this document) will be mandatory upon the effective date of this regulation.

FDA agrees that education is an important factor in providing instructions on food safety. Thus, the agency intends to develop an educational and outreach campaign related to this final rule to inform the public, including both consumers and food service employees.

(Comment 22) Several comments pointed out that many existing egg cartons already bear safe handling instructions. To eliminate costly relabeling, these comments requested that FDA permit existing safe handling label statements if they meet or exceed the statement required by the final rule. One comment requested that if a carton already has a ''keep refrigerated'' label on the carton that it be allowed to delete the phrase from the safe handling statement.

The agency is not persuaded to exempt eggs that have existing safe handling instructions from requirements in § 101.17(h)(1). FDA has concluded that prescribing the language for a safe handling statement for shell eggs would give consumers a clear and consistent message and provide a ''level playing field'' for industry by requiring that all products covered by the regulation bear the same information. Further, FDA concludes that a prescribed safe handling statement would ensure a message that is not misleading or confusing.

In addition, the agency is not persuaded to delete the phrase ''keep eggs refrigerated'' from the safe handling statement on cartons that already have a keep refrigerated statement. The agency recognizes that many cartons already have refrigeration instructions and notes that USDA requires in 9 CFR 590.50 that eggs packed for the ultimate consumer be labeled to indicate that refrigeration

is required. However, FDA believes that the refrigeration instruction is an essential component of the safe handling statement and, as such, should not be taken out of the context of the rest of the statement. Further, FDA's safe handling statement permits manufacturers to uniformly comply with both FDA's safe handling statement and FSIS' refrigeration labeling requirement because FSIS' requirement is that cartons be labeled to indicate that refrigeration is required. Consequently, this safe handling statement can replace that required by FSIS. The agency recognizes the redundancy in having two refrigeration statements and points out that, while firms are revising labels to add the safe handling statement, they can delete the additional ''keep refrigerated'' statement that is not a part of the safe handling statement required in § 101.17.

Although FDA is not exempting eggs that have existing safe handling instructions from requirements in § 101.17(h)(1), the agency does see merit in using enforcement discretion with firms that want to exhaust existing labels provided that the labeling meets or exceeds the requirement for the instructional element, which includes: (1) A refrigeration instruction and (2) a cooking instruction. FDA believes that this would reduce the costs for some firms while still providing consumers information on how to properly handle eggs. Firms with existing inventories as of the effective date of this final rule may exhaust those inventories as long as they contain the essential elements listed above. Upon their next printing, however, these firms must comply with the requirements in § 101.17(h)(1).

Lastly, the agency is revising proposed § 101.17(h)(1) and deleting proposed § 101.17(h)(6) to be consistent with the changes made in § 115.50 (as discussed in section III.C of this document). The remainder of § 101.17(h) is renumbered to reflect this change.

C. Comments on Effective Date

(Comment 23) A few comments asserted that the implementation time for the proposed labeling requirement is insufficient. These comments maintained that given the logistics of redesigning cartons, replacing inventory, making necessary adjustments to distribution channels, and accommodating seasonal product demand fluctuations, the egg industry needs a 360-day

implementation period. According to one comment, once the rule is finalized, new designs will need to be developed, then sent to customers for label approval. The comment stated that production of the label could not take place until the design is approved, which according to the comment, could take 60 to 90 days. The comment maintained that once production begins, it will involve label changes for thousands of stockkeeping units (SKU's) of hundreds of different customers, which would be a burden given only the approximately 90 days left to comply. The comment estimated that personnel would take 11,386 to 19,880 hours to redesign the label; retool all carton labels, including artwork; communicate with customers; order plates; and complete other required activities.

Further, the comment contended that it is not likely that egg producers will have begun to use the proposed statement before the compliance date in order to take advantage of FDA's willingness, as stated in the proposal (64 FR 36492 at 36510), to allow producers to use the safe handling statement as proposed and if printed before the publication of the final rule. The comment asserted that producers would not want to take the chance of changing labels twice. The comment explained that egg carton stock is prepared well in advance and customers' needs may be less than expected. Therefore, if cartons are not used prior to the effective date, they will need to be discarded. The comment stated that, on the other hand, a large inventory may be needed to accommodate peak periods, such as Christmas and Easter and if large stocks are not maintained, the inventory may run out. Additionally, the comment expressed concern that, depending on when the rule is published, the labeling requirement could be implemented during the time of peak production, and, therefore would make compliance with the requirement extremely difficult. Another comment disagreed with FDA's assessment that a longer compliance period would delay benefits of the rule because many cartons currently contain safe handling instructions and, therefore, benefits are being realized now.

The agency notes that the purpose of the safe handling labeling requirement is to protect the public health by providing consumers with material information, i.e., instructions on how to

safely handle and prepare eggs in order to reduce the risk of illness. Therefore, FDA believes that the safe handling statement should be placed on egg cartons as soon as possible. However, FDA is persuaded by the comments that it may be extremely burdensome for some producers to comply with the labeling requirements in 180 days. The agency acknowledges the difficulty in designing new labels, receiving label approval from customers, and building up inventories. The agency also recognizes the costliness of destroying inventories that do not comply with FDA's requirements. The agency is persuaded by the economic concerns raised in the comments that it should provide some flexibility to manufacturers. As discussed below in more detail in section IV.A of this document, the longer compliance period will generate savings in costs that would exceed the reduction in benefits thus still meeting the agency's need to address the public health concern. Therefore, FDA is providing an additional 90 days for firms to come into compliance with the requirements in § 101.17(h).

III. Refrigeration of Shell Eggs in Retail Establishments

As discussed in section II of this document, SE in eggs is a significant public health concern. As discussed in the proposal, FDA concluded that one practicable measure to limit the number of viable SE in shell eggs is refrigeration because it extends the effectiveness of the egg's natural defenses against SE and slows the growth rate of SE. USDA published a final rule (63 FR 45663, August 27, 1998) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7.2 °C (45 °F). This regulation, however, does not apply to eggs while held at all retail establishments. FDA is concerned that without continued refrigeration up until the time that the eggs are cooked, there would be an opportunity for the egg's defenses to degrade and growth of SE to occur. The agency reviewed research indicating that SE multiplies at temperatures of 10 °C (50 °F) and above but can be inhibited at lower temperatures, e.g., 8 °C (46 °F), 7.2 °C (45 °F) and 4 °C (39 °F). Based on this research and USDA's temperature requirement during transport, FDA proposed a maximum ambient temperature of 7.2 °C (45 °F) for eggs stored and displayed at retail establishments.

A. Refrigeration Temperature Requirements

(Comment 24) Most comments regarding the proposal to require refrigeration of shell eggs supported a requirement for refrigeration. Some of these comments supported the proposed maximum temperature requirement, i.e., 7.2 °C (45 °F), whereas other comments disagreed with this temperature requirement. Several comments suggested that the agency set the maximum ambient temperature for shell eggs held at retail at 5 °C (41 °F), instead of 7.2 °C (45 °F). Some of these comments suggested that this would provide a margin of safety, especially for eggs packed tightly together in large trays or in large retail coolers. Other comments noted that a requirement of 5 °C (41 °F) would ensure consistency with the requirement in FDA's Food Code that potentially hazardous foods be refrigerated at 5 °C (41 °F) (Ref. 5).

The agency is not persuaded that the temperature requirement should be 5 °C (41 °F), rather than 7.2 °C (45 °F). As discussed in section I.F of the proposal, research indicates that SE multiplies at temperatures of 10 °C (50 °F) and above but that multiplication is inhibited at lower temperatures. Therefore, by requiring a refrigeration temperature lower than 10 °C (50 °F), the agency is already providing a margin of safety for shell eggs. FDA concludes that refrigeration at 7.2 °C (45 °F), i.e., the same temperature required by USDA under the Egg Products Inspection Act (EPIA) for the storage and transportation of shell eggs, is sufficient to protect the public health. Because eggs cool down only slightly faster when held at 5 °C (41 °F) as opposed to 7.2 °C (45 °F), as discussed in the PRIA (64 FR 36516 at 36518), requiring eggs to be stored at the lower temperature would have a negligible effect on the SE risk. Requiring a temperature of 5 °C (41 °F) as the maximum ambient temperature would increase costs to the producer without producing significant additional food safety benefits.

Furthermore, the agency notes that the storage temperature of shell eggs addresses growth of SE in shell eggs, whereas the refrigeration temperature required by the Food Code, i.e., 5 °C (41 °F), addresses growth of all pathogens that may be present in potentially hazardous foods. Thus, in addressing holding temperatures for potentially hazardous foods in general, the Food Code

requires a temperature for retail storage that will prevent or slow the growth of most pathogens, including cold-tolerant pathogens such as *Listeria monocytogenes* that have been shown to grow at 5 °C (41 °F). The agency does not have data suggesting that *L. monocytogenes* or other pathogens are a potential concern in shell eggs. The agency concluded that a maximum storage temperature of 7.2 °C (45 °F) will be effective in inhibiting the growth of SE that may be present in shell eggs. Of course, this requirement does not preclude States or retailers from maintaining shell eggs at lower refrigeration temperatures.

(Comment 25) One comment contended that FDA based the 7.2 °C (45 °F) ambient temperature requirement on studies that do not provide a sound scientific foundation for the requirement. The comment stated that none of the articles FDA cites in support of the proposed refrigeration requirement examined SE growth in eggs stored under conditions that simulate actual commercial storage conditions. The comment maintained that, because commercially stored egg cartons are often placed on pallets in large numbers and stacked to high levels in high-volume coolers, the eggs' internal temperature may be substantially higher than the coolers' ambient temperature, especially for centrally located eggs that are insulated by surrounding eggs and, therefore, exposed to warmer temperatures.

FDA disagrees with the comment. The studies noted by the comment were not cited as evidence that eggs in commercial storage conditions would achieve a certain temperature when refrigerated. Rather, these studies provide evidence that SE growth is inhibited when eggs are at the temperature studied. While the agency agrees that eggs packed near the center of a large pallet may not cool as quickly as those near the perimeter, the temperature of eggs, when refrigerated, will progress towards the ambient temperature of the refrigeration unit. As discussed above in this section, FDA has provided its rationale for why an ambient temperature of 7.2 °C (45 °F) for storage of eggs is the best available option for protecting the public health.

(Comment 26) One comment recommended that States be allowed to require ambient temperatures lower than 7.2 °C (45 °F) for shell eggs if they believe their citizens will be better

protected by a lower temperature, such as 5 °C (41 °F), particularly if gaps exist in the scientific data on this issue.

The agency recognizes that some States and localities may have temperature requirements lower than 7.2 °C (45 °F). As stated in the proposal (64 FR 36492 at 36499), the agency does not intend that this regulation would preempt recommendations of the Food Code or other State or local requirements that require a lower temperature. The regulation would, however, preempt any State or local requirements that allow a temperature greater than 7.2 °C (45 °F).

(Comment 27) One comment supported the 7.2 °C (45 °F) ambient temperature requirement, but urged the agency and others to communicate effectively with retail establishments to minimize any confusion that may result from the temperature difference between this proposed requirement and the requirement in the Food Code.

While the new temperature requirement may create some confusion initially, the Food Code will be revised to reflect this new temperature for storage of shell eggs in its next reprinting (currently anticipated to be 2001). The revision will include not only the new temperature requirement, but also the scientific references and public health reasons for the change in annexes 2 and 3, respectively, of the Code. In the meantime, FDA will rely, as it has in the past, on State and local authorities to assist retail establishments in complying with the agency's regulations. The agency holds annual training courses for State personnel and food service directors that focus on changes in the Food Code. FDA will work closely with the States to ensure that they communicate effectively with retail establishments to minimize any confusion that may result from the temperature difference between this requirement and the requirement in the 1999 Food Code and to ensure that compliance assistance is consistent nationwide.

(Comment 28) One comment supported the refrigeration of shell eggs at 7.2 °C (45 °F) provided that minor variations in ambient temperature do not result in condemnation of eggs. The comment suggested that FDA make refrigeration mandatory, but make the temperature of 7.2 °C (45 °F) a voluntary standard, or establish a level of temperature variation (e.g., 5 °F) that would

be tolerated before the eggs would be subject to regulatory action. Another comment objected to the fact that FDA made no provision in its proposal for eggs that are out of compliance for a limited amount of time, and suggested that the allowance of a reasonable amount of time to place eggs in a cooler after delivery would not compromise their safety.

FDA disagrees with the comment that the temperature for refrigeration of eggs be a voluntary standard, rather than a mandatory requirement. The agency has proposed 7.2 °C (45 °F) as the maximum ambient temperature for storage and display of shell eggs at retail establishments. Realizing that minor variations in ambient temperature are unavoidable, retailers may choose to maintain shell eggs at temperatures below the maximum established temperature to provide for a margin for variation. As with any regulation, the enforcement of this temperature requirement will depend on the particular circumstances regarding the situation (including the temperature of the eggs themselves) as well as the discretion of the agency. In § 115.50(b)(1), FDA provided that ''shell eggs held for retail distribution shall promptly be placed under refrigeration * * * upon receipt at a retail establishment.'' The agency believes that retailers should make every effort to promptly place shell eggs under refrigeration upon receipt. In most cases, this can be done. However, FDA recognizes that there may be some circumstances in which short delays are unavoidable. For example, when eggs are delivered to a grocery store, the stock clerk responsible for moving the eggs into the cooler could be briefly delayed in the task because he is cleaning up after an accident in one of the aisles involving a glass breakage. To allow for a practical application of the refrigeration requirement in such situations, FDA is adding a provision to § 115.50(b)(1) that provides that where short delays are unavoidable, the eggs should be placed under refrigeration as soon as reasonably possible.

B. Enforcement of the Refrigeration Requirement

(Comment 29) One comment expressed concern that consequences for violation of FDA's refrigeration requirement are inconsistent with violation of FSIS' refrigeration requirement for shell eggs during transportation. The comment noted that FSIS issues a facility violation but does not

retain the product if eggs are found to be held above 7.2 °C (45 °F), whereas FDA would require diversion or destruction of the eggs.

As set out in the final rule, FDA has the authority, under sections 301 and 402(a)(4) of the FD&C act, to seize eggs that are held at retail at an ambient temperature above 7.2 C (45 F), on the grounds that those eggs have been held under insanitary conditions whereby they may be rendered injurious to health and are, therefore, adulterated. FDA may also use administrative procedures set out in this rule to order that the eggs that have been held in violation of the 7.2 C (45 F) requirement established in this rule, be destroyed or diverted. FSIS has the authority, under the EPIA, to detain eggs that are transported at an ambient temperature above 7.2 C (45 F), pending judicial seizure. FSIS also has the option of seeking civil money penalties against violators of the transport temperature requirement. The two agencies will coordinate enforcement efforts as closely as the different statutes allow. Both agencies agree that enforcement of the temperature requirement will depend on the particular circumstances regarding the situation (including the temperature of the eggs themselves) as well as the discretion of each agency.

(Comment 30) Two comments stated that they oppose complete preemption of State and local egg safety provisions. One of these comments from an association of State food and drug officials agreed that temperature requirements should be uniform, but also argued that the States should be free to enforce equivalent State requirements under State laws and regulations. This comment also stated that States should be permitted to require refrigeration temperatures lower than 7.2 °C (45 °F).

In the proposal, FDA tentatively concluded that the regulation should preempt less stringent State and local requirements because allowing them would interfere with the important public health objective of refrigerating eggs at 7.2 °C (45 °F). FDA does not intend that this regulation preempt State requirements that are the same as or more stringent, i.e., 7.2 °C (45 °F) or lower. The regulation does, however, preempt any State or local temperature requirements greater than 7.2 °C (45 °F). FDA would like to clarify that States will be permitted to enforce their own temperature

requirements that are equivalent to or lower than FDA's proposed requirement. For example, if a State has a temperature requirement of 5 °C (41 °F) and eggs were found at a storage temperature of 6.7 °C (44 °F), then the eggs would be in compliance with the Federal regulations, but not the State regulations and the State could take enforcement action to enforce its own regulations.

(Comment 31) One comment also opposed preemption of State administrative procedures. The comment asserted that, the administrative procedures provided in the proposal would impose a lengthy process on States and localities. The comment maintained that it is doubtful that State or local jurisdictions would follow FDA's proposed procedures, e.g., they would not call FDA district or regional directors to remove adulterated eggs from establishments traditionally under their jurisdiction. Nevertheless, the comment asks for clarification on whether the proposed regulations preempt State administrative procedures.

The agency is clarifying that the administrative procedures in proposed § 115.50 do not preempt State or local administrative procedures. On the contrary, FDA explicitly provides in § 115.50(d) that State and localities may follow the hearing procedures set out in § 115.50(e) substituting, where necessary, appropriate State or local officials for FDA officials, or they may follow comparable State and local procedures as long as such procedures satisfy basic due process. Thus, FDA intends that States could use their own administrative procedures to enforce the regulation. FDA is removing the word ''comparable'' to make it clearer that State and local administrative procedures do not need to track FDA's procedures.

(Comment 32) One comment raised concerns about the breadth of the preemptive effect of the proposed regulation. It questioned whether the proposed rule might preempt all State laws relating to egg safety and substitute FDA's regulation. This comment contended that States already have systems in place that expeditiously remove unsafe foods from commercial channels and that those should not be preempted.

FDA agrees with the comment. States do have systems already in place that expeditiously remove adulterated food from the marketplace. In the proposal, FDA acknowledged that States

and localities, more than FDA, currently enforce regulations in retail establishments. When examining options for the enforcement of refrigeration requirements, FDA tentatively concluded that a Federal-State cooperative approach would be the best approach to enforce the refrigeration requirements. Thus, FDA proposed to allow States and localities to enforce the Federal regulation, along with FDA, if the States and localities so desired.

FDA wants to make it very clear that the intended preemptive effect of this regulation is very narrow. FDA does not intend to preempt general food safety laws that apply to eggs, such as State food and drug acts, or State or local laws, regulations, or ordinances applying to retail establishments, e.g., the Food Code. A State or local food safety agency can continue to enforce its own refrigeration requirements or other egg safety requirements under its own administrative or judicial enforcement procedures as long as the retail refrigeration requirements for eggs are (equal to or less than 7.2 °C (45 °F). FDA is including State and local agencies in the enforcement of this regulation to broaden their enforcement tools, not to narrow them. To ensure that the limited preemptive effect of these regulations is clear, FDA has added a statement on the preemptive effect of the regulations to the codified text.

(Comment 33) A comment contended that the provisions in the proposal that allow States and localities to enforce the provisions ''until FDA notifies the State or locality in writing that such assistance is no longer needed'' appear to place State regulatory actions subordinate to those of FDA. The comment maintained that it knew of no other situation where regulatory actions of State or localities constituted ''assistance'' to a Federal agency, especially when intrastate commerce is involved. The comment asked for clarification of this issue.

The provision that allows State and local agencies to enforce FDA's regulations draws its terms from section 311 of the Public Health Service Act (PHS Act). FDA does not consider State and local food safety activities to be subordinate to Federal activities. In fact, FDA created this cooperative model to ensure that State and local officials continue to be the primary enforcement

officials in retail establishments while being provided the ability to enforce this Federal requirement for egg refrigeration.

(Comment 34) One comment also expressed concern regarding the precedent of using the PHS Act for enforcement of communicable disease regulations when there are other collaborative and integrated mechanisms available, e.g., the Food Code. The comment maintained that many States adopt the provisions of title 21 of the *Code of Federal Regulations* (CFR) and, therefore, the comment noted that it previously requested that FDA adopt relevant sections of the Food Code as regulations. The comment asserted that adopting relevant sections of the Food Code as a Federal regulation would lower the risk of illness, while promoting uniformity without preempting State and local authority.

The agency notes that this regulation is not the first regulation issued by FDA that utilized the PHS Act to address prevention of communicable diseases. FDA used the PHS Act as its legal authority to issue: (1) Regulations to control the interstate shipment of molluscan shellfish (21 CFR 1240.60); (2) regulations to control the interstate and intrastate commerce of turtles (§ 1240.62 (21 CFR 1240.62)); (3) requirements for mandatory pasteurization of milk and milk products (21 CFR 1240.61); and regulations to control blood and tissue products (21 CFR 640 and 1270). However, the agency acknowledges that this regulation represents a new approach to food safety as it relates to matters traditionally addressed by the States. The agency believes that the Federal-State cooperative approach that it is adopting in this final rule for the regulation of eggs is the most effective and efficient use of Federal, State, and local food safety authorities.

Further, FDA recognizes that many States adopt parts of 21 CFR by reference. However, the agency is not persuaded by the comment that it should adopt relevant sections of the Food Code in lieu of issuing this regulation. FDA notes that its policy on the refrigeration of eggs, i.e., that refrigeration at 7.2 °C (45 °F) is adequate to maintain the safety of shell eggs would be the same whether or not the agency issued rulemaking to codify in 21 CFR sections of the Food Code relevant to shell eggs. Nevertheless, as announced in the Egg Safety Action Plan, the

agency plans to take additional steps to protect at-risk consumers by establishing safe egg handling and preparation practices at retail, consistent with provisions in the Food Code.

(Comment 35) One comment contended that FDA should evaluate each State and local program to ensure that they have the expertise and resources to enforce the regulations. This comment contended that if the States and local programs do not have the capability to enforce the rule, FDA should provide training or resources, or enforce the rule itself. Furthermore, the comment stated that FDA should perform comprehensive annual reviews and permit only those agencies that satisfy strict performance standards to continue to enforce the rule.

FDA disagrees with this comment. As discussed in the proposal, the agency recognizes that the inspection of retail establishments traditionally has been the province of State and local food safety agencies. FDA expects that these agencies would continue to inspect these establishments and will be able to enforce the refrigeration requirement. FDA considered a requirement that the States report to FDA on their enforcement activities. However, the agency concluded that, because of the vast number of food safety agencies at the State and local level, reporting to FDA would be too resource intensive. Further, the agency concluded that requiring States and localities to report to FDA would remove valuable resources from egg safety enforcement and place them into administrative activities. Consequently, FDA decided to not require enforcement reports from State and local agencies. Moreover, FDA, in keeping with the principles of Executive Order 13132 on federalism, thought it prudent to allow States the maximum administrative discretion possible in enforcing this rule. However, the agency intends to stay informed of the enforcement of State and local agencies. Where State or local coverage needs to be augmented, FDA intends to act.

(Comment 36) One comment opposed the allowance of 10-working days after the order is given for the destruction of eggs that are not in compliance with the temperature requirement as proposed in § 115.50(e)(1)(i). This comment maintained that FDA provided no rationale for the time period. Moreover, the comment contended that 10 days was an unnecessarily long period

of time and could allow for inadvertent repacking. The comment suggested that only 3 to 5 days be allowed.

The agency disagrees with the comment. The time period of 10-working days is consistent with other regulations that address the prevention of communicable disease, e.g., regulations in § 1240.62 that control the interstate and intrastate commerce of turtles. Moreover, the agency believes that 10-working days allows sufficient time for interested parties to appeal the detention order as provided in § 115.50(e)(2)(i). In addition, the agency points out that the administrative procedures provide for sufficient safeguards against inadvertent repacking of shell eggs that were not held in compliance with the temperature requirement. Section 115.50(e)(1)(iv) provides that eggs that are detained be labeled with official tags stating that they not be sold, distributed, or otherwise disposed of except that they be diverted or destroyed, or moved pending appeal. The comment did not persuade FDA that there is sufficient cause to be concerned that eggs will be inadvertently repacked if they are held for 10-working days before they are destroyed or diverted. Thus, the agency is retaining the provision in § 115.50(e)(1)(i) for 10-working days before eggs are diverted or destroyed.

(Comment 37) One comment suggested that inspectors check the temperature of the shell eggs' environments at least twice a year. The comment also suggested that, to ensure that retail establishments are maintaining accurate temperatures, continuous temperature recording devices be required and records made available to inspectors.

The agency agrees that the inspection of retail establishments twice a year is reasonable. In fact, the Food Code recommends that retail establishments be inspected once every 6 months. These inspections include checking the temperature at which potentially hazardous foods, including eggs, are being held. However, the agency does not find that it is necessary to make the inspection a requirement as part of this rulemaking. The agency expects that when State and local agencies routinely inspect retail establishments, they will check the temperature at which shell eggs are held. In addition, for any establishment that FDA inspects, it will also check the temperature at

which shell eggs are held. Thus, FDA is not persuaded by the comment to require a specific interval for checking the temperature at which shell eggs are held.

FDA disagrees that it should require that retail establishments maintain continuous recording devices. The agency notes that neither the Food Code nor FSIS, in its directive regarding the enforcement of refrigeration requirements for shell eggs (Ref. 8), recommends that such devices be used. Furthermore, FDA notes that requirement of such devices may be very costly, especially for small businesses. Consequently, the agency is not persuaded by the comment to require establishments to maintain continuous recording devices.

C. Other Changes to the Proposal

FDA is revising proposed § 115.50 by deleting paragraph (d) and revising paragraph (b) for clarification. The agency concludes that § 115.50(d) stating that the requirements of this section apply to all eggs may be confusing in light of the fact that paragraph (b) states that all requirements of the section, except paragraph (c) apply to shell eggs. FDA is revising paragraph § 115.50(b) to state ''except as provided in paragraph (c) of this section; shell eggs held for retail distribution, whether in intrastate or interstate commerce, shall bear the following statement: '' With this revision, § 115.50(d) becomes redundant. The rest of the section is renumbered to reflect this change.

IV. Final Regulatory Impact Analysis

A. Benefit-Cost Analysis

FDA has examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, safety, distributive, and equity effects). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy

of $100 million; adversely affecting some sector of the economy in a material way; or adversely affecting jobs or competition. A regulation is also considered a significant regulatory action under Executive Order 12866 if it raises novel legal or policy issues. Under the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requiring cost-benefit and other analyses, a significant rule is defined in section 1531(a) as ''a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any 1 year * * *.'' Finally, the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

FDA finds that this final rule is economically significant under Executive Order 12866. FDA determined that this final rule, based on the median estimate of cost contained in the economic analysis, does not constitute a significant rule under the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Furthermore, in accordance with the Small Business Regulatory Enforcement Fairness Act of 1995 (Public Law 104–121) FDA determined that this final rule will be a major rule for the purpose of congressional review.

This section contains the regulatory impact analysis of the final rule. A more complete analysis and a list of references is available in a separate document entitled ''Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rule to Require Refrigeration of Shell Eggs at Retail and Safe Handling Labels'' (64 FR 36516, July 6, 1999).

FDA received no comments that directly addressed the cost-benefit analysis of the proposed rule. Several comments, however, discussed aspects of the rule that would affect the cost-benefit analysis. In this final regulatory impact analysis, FDA responds to those comments.

1. Regulatory Options

FDA considered several regulatory options for dealing with SE in shell eggs. The options considered include: (1) No new regulatory action, (2) labeling only, (3) refrigeration at 7.2 °C (45 °F) only, (4) refrigeration at 5 °C (41°F), (5) labeling and refrigeration as proposed, (6) HACCP for shell eggs, (7) in-shell pasteurization, (8) longer compliance periods, and (9) limited retail sell-by periods. FDA received comments on the proposal that directly or indirectly dealt with the economic analyses of some of these options.

(Comment 38) Several comments discussed the costs of in-shell pasteurization (option 7). In the analysis of the proposal, FDA assumed that the annual cost of pasteurization was $0.30 per dozen eggs. If 47 billion shell eggs were consumed per year, the annual cost of pasteurizing all of them would be about $1.2 billion. One comment estimated the cost to be $0.26 to $0.38 per dozen eggs, which implies that the annual cost of pasteurizing 47 billion shell eggs would be $1 to $1.5 billion. Another comment estimated that pasteurization would increase the price of a dozen eggs by 35 to 40 percent. The comment listed no prices, but at an average price of $0.80, the additional cost of pasteurizing 47 billion eggs would be $0.28 to $0.32 per dozen, or $1.1 to $1.3 billion per year. FDA did not estimate the transition, or set-up costs, (e.g., costs of equipment, redesign of processing facilities, training) for processors switching to pasteurization, so these estimates understate the full cost of in-shell pasteurizing all shell eggs.

Although in-shell pasteurization would greatly reduce SE, the agency concludes that other interventions between farm and table will reduce SE at lower cost. The egg safety action plan includes these other interventions, such as on-farm controls, controls at packer/processor, and retail controls, in addition to in-shell pasteurization.

(Comment 39) Several comments requested a longer compliance period for the new egg label.

The main disadvantage of longer compliance periods for the labeling provision (option 8) is that the option would delay the realization of the benefits of the rule. In this final rule, the agency will allow 9 months (instead of the proposed 6 months) for producers to comply with

the labeling provision. The longer compliance period will probably generate savings in costs that exceed the reduction in benefits (as measured with the revised CDC surveillance baseline). FDA discusses the effects of the longer compliance period in more detail in the sections on benefits and costs.

2. Benefits

Benefits from the final rule to require a safe handling label and the refrigeration of shell eggs at 7.2 °C (45 °F) come from reducing egg-related illness. The formula FDA used for estimating benefits is:

Marginal health benefits = baseline risk (number of SE illnesses related to shell eggs) x expected reduction in the number of illnesses brought about by the final rule x health cost per illness.

(Comment 40) Although there were no comments directly on the estimated benefits, several comments argued that FDA used too high a baseline number of SE illnesses. In addition, some comments cited new data from CDC on SE. In the economic analysis in the proposal, FDA used the results of the USDA SE risk assessment for one estimate of the baseline risk and the CDC *Salmonella* surveillance data for another estimate of the baseline (64 FR 36516 at 36520). The CDC active surveillance data showed a 44 percent fall in SE between 1996 and 1998 (Ref. 9). CDC also released a new estimate of the total number of illness associated with *Salmonella* (Ref. 10). The new estimate of the total number of illnesses from *Salmonella* is lower than previous estimates, which implies that the baseline number of SE-related illnesses is also lower. In response to the comments on FDA's baseline number of illnesses, FDA adjusted the CDC surveillance baseline to incorporate the recent CDC surveillance data and estimated number of SE-related illnesses.[2] The SE risk assessment model baseline did not use CDC cases, so it does not change.

[2] In the analysis of the proposed rule, FDA estimated the number of SE illnesses from shell eggs with a Monte Carlo simulation. In one simulation, FDA used CDC surveillance data from 1988 through 1997 to calculate that the annual average number of SE isolates was 8,400. FDA then applied the probability that an isolate would be

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Table 1 of this document shows the USDA SE risk assessment baseline, the FDA-modified USDA SE risk assessment baseline (for explanation of this modification, see footnote 1 in section II.A.8 of this document), the CDC surveillance baseline, and the adjusted CDC surveillance baseline.

TABLE 1.—FOUR ANNUAL ILLNESSES FROM ESTIMATES OF SALMONELLA ENTERITIDIS (SE) IN SHELL EGGS

	5th Percentile	Median	Mean	95th Percentile
a. USDA SE Risk Assessment				
Illnesses	126,374	504,082	661,633	1,742,592
Arthritis	3,631	14,864	19,994	55,915
Deaths	68	301	391	1,050
b. USDA SE Risk Assessment as Modified by FDA				
Illnesses	115,645	416,156	569,231	1,508,814
Arthritis	3,372	12,548	17,175	48,594
Deaths	66	250	354	985
c. CDC Surveillance Model				
Illnesses	63,884	189,599	191,511	319,275
Arthritis	1,330	5,533	5,727	12,202
Deaths	37	122	115	197
d. Revised CDC Surveillance Model				
Illnesses	36,523	112,138	114,271	194,796
Arthritis	762	3,011	3,410	7,251
Deaths	21	66	68	117

FDA used the USDA SE risk assessment model to estimate the expected reduction in illnesses attributed to the rule. The design of the USDA SE risk assessment model allowed the agency to estimate the number of illnesses prevented by comparing the baseline number of illnesses with the number of illnesses under the rule.

FDA calculated the health cost per illness prevented by classifying SE illnesses by the severity of outcome: Mild, moderate, and severe acute gastrointestinal illnesses; resolved and chronic

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reported that was used in the USDA SE risk assessment, i.e., 0.014, to estimate the total number of SE cases. FDA assumed, based on outbreak and other information, that 10 to 60 percent of all SE cases were associated with shell eggs. In the revised CDC surveillance model, FDA used CDC surveillance data from 1989 through 1998 to calculate an average annual number of SE isolates of 8,300. The agency applied the probability of reporting used in the new CDC foodborne illness estimates, 0.026, to estimate the total number of SE cases (Ref. 10). As in the proposed rule, FDA assumed that 10 to 60 percent of all SE cases were associated with shell eggs. Part d of table 1 shows the results of the simulation based on the revised CDC data.

reactive arthritis; and death. The agency then multiplied the estimated monetary health cost per type of illnesses by the number of illnesses prevented of each type. FDA calculated total health benefits from the final rule with the following formula:

Total health benefits = (number of mild cases prevented x $ per case) + (number of moderate cases prevented x $ per case) + (number of severe-acute cases prevented x $ per case) + (number of resolved cases of arthritis prevented x $ per case) + (number of chronic cases of arthritis prevented x $ per case) + (number of deaths x $ per death).

The baseline risk, the expected reduction in risk, and the health costs per illness are all uncertain. FDA, therefore, estimated a distribution of possible health benefits for the final rule, with the distribution based on the probability distributions associated with the main uncertainties. FDA estimated that this final rule would reduce the number of egg-related illnesses by 6 to 49 percent (5th to 95th percentile), with the median equal to 14.5 percent and the mean equal to 19 percent. The ranges (5th to 95th percentile) of estimated annual benefits for the three baselines are shown in table 2 of this document.

TABLE 2.—TOTAL ANNUAL HEALTH BENEFITS FROM THE REDUCTION IN SALMONELLOSIS ATTRIBUTABLE TO THE PROPOSED SHELL EGG RULES: USDA[1] SE[2] RISK ASSESSMENT BASELINE, CDC[3] SURVEILLANCE BASELINE, AND ADJUSTED CDC SURVEILLANCE BASELINE

Variable	5th Percentile	Median	Mean	95th Percentile
a. Modified USDA SE Risk Assessment Baseline				
Illnesses prevented	12,369	65,801	115,848	407,064
Health benefits	$86.7 million	$703 million	$1,700 million	$6,610 million
b. CDC Surveillance Baseline				
Illnesses prevented	7,032	25,132	36,937	107,230
Health benefits	$49.2 million	$303 million	$501 million	$1,679 million
c. Revised CDC Surveillance Baseline				
Illnesses prevented	3,925	14,958	21,961	62,991
Health benefits	$32.9 million	$259.5 million	$466.3 million	$1,619 million

[1] USDA means U.S. Department of Agriculture.
[2] SE means *Salmonella* Enteritidis.
[3] CDC means the Centers for Disease Control and Prevention.

FDA estimated the benefits derived from extending the compliance period for the labeling regulation. With the longer compliance period for the labeling provision, some of the labeling benefits will be postponed for 3 months. In the analysis of the proposal, the agency estimated

the median benefits attributable to labeling alone to be $261 million using the USDA SE risk assessment baseline and $103 million using the CDC surveillance baseline. With the revised CDC surveillance baseline, median labeling benefits are $91 million. FDA used a 7 percent rate of discount to estimate the reduction in benefits from increasing the compliance period for labeling by 3 months. The later effective date will reduce median health benefits by, at most, $5 million under the USDA SE risk assessment baseline and $2 million under either version of the CDC surveillance baseline because some labels would be in place before the effective date. Because it is based on more recent information, the agency believes that $2 million is the best estimate of the reduction in benefits associated with the later effective date for the safe handling label.

The benefit estimates above depend on a number of assumptions including assumptions about individual response to the egg labels. Modification of these assumptions would lead to changes (increases or decreases) in the estimate of the benefits of this rule.

3. Costs

FDA received no comments on the estimated costs of this rule and, therefore, will use the same estimate reported in the analysis of the proposal. The costs of the final rule are the sum of the costs of changes in manufacturing practices—labeling and refrigeration—and changes in consumer practices—egg preparation and consumption.

a. *Labeling*. The costs of labeling are the sum of inventory disposal, label redesign and administrative costs. FDA calculated labeling costs with the following model:

Labeling cost = ($ administrative costs per firm x number of affected firms) + ($ value of cartons manufactured x disposal percentage of carton inventory) + (number of affected labels x $ redesign cost per label).

In the analysis of the proposed rule, FDA estimated the total cost of labeling for a 6-month compliance period to be a one-time cost of approximately $18 million. The cost included administrative costs, inventory disposal costs, and label redesign costs. Several comments stated that inventory and redesign costs would be high, but did not state whether the cost estimates FDA

presented were high. One comment from a carton manufacturer stated that redesign costs for its foam labels would be $2 million. Based on the market share cited in the comment, the cost per SKU would be about $500, which is the cost used in the proposal for a 6-month compliance period.

Another comment stated that in order to print on the sides of cartons manufacturers of smaller egg cartons would have to purchase new equipment costing several million dollars. The agency disagrees that such purchases will be necessary. With redesign and reduced type size for non-mandatory material, sufficient free space will be available for the safe handling statement without the need to print on the sides of the cartons. The shorter safe handling statement in this final rule (compared to the statement in the proposal) increases the agency's confidence that smaller egg cartons will have sufficient space.

In light of FDA's decision to extend the compliance period to 9 months, labeling costs will decrease. In the analysis of the proposal, FDA compared a 6-month compliance period with a 12-month compliance period. FDA now assumes that the labeling costs for a 9-month compliance will be about halfway between the costs for 6- and 12-month periods. As table 3 of this document shows, this assumption leads to estimated costs of $15 million.

TABLE 3.—ESTIMATED TOTAL COSTS TO INCORPORATE SAFE HANDLING STATEMENTS (TOTAL COSTS ROUNDED TO NEAREST MILLION)

Compliance Period	6 Months	9 Months	12 Months
Total administrative costs	$280,000	$240,000	$200,000
Total inventory disposal costs	$3,000,000	$2,250,000	$1,500,000
Total label redesign costs	$15,000,000	$12,500,000	$10,000,000
Total labeling costs	$18,000,000	$15,000,000	$12,000,000

FDA believes that the 9-month compliance period combined with the shortening of the safe handling statement may reduce labeling costs by more than the $3 million difference shown in table 3. The shorter statement should eliminate many of the problems associated with fitting the statement on cartons with limited flat space. With 3 more months for compliance, many more establishments will be able to use up all of their carton inventories before the effective date.

b. *Refrigeration*. FDA estimated the refrigeration costs to be the cost of the additional equipment required for all establishments to maintain an ambient temperature of 7.2 °C (45 °F). The agency calculated the cost by multiplying the estimate of the number of establishments that would require new (or upgraded) equipment by the cost of equipment. FDA estimated the number of establishments that would require new equipment by assuming that no establishments in States that have adopted the Food Code and some fraction—with one-third the most likely—of establishments in States that have not adopted the Food Code would require new equipment. FDA used industry sources to obtain estimates of the range of costs of new or additional equipment necessary to meet the refrigeration provision of the final rule. The estimated costs per establishment ranged from close to zero for small equipment upgrades to $6,000 for a large new refrigerator.

FDA estimated a distribution of the total possible refrigeration costs for the final rule. The range (5th to 95th percentile) of estimated one-time refrigeration costs was $7 million to $228 million, with a median of $31 million.

c. *Changes in consumer practices*. FDA estimated the annual costs to consumers of changing the way eggs are prepared and consumed as:

Cost of changes in consumer practices = annual number of eggs consumed x baseline fraction of eggs consumed undercooked x fractional reduction in undercooked eggs in response to safe handling label x $ value of undercooking one egg.

This cost to consumers is uncertain. The range (5th to 95th percentile) of annual costs was $2 million to $20 million, with a median of $10 million. The cost of changes in consumer practices is an annual recurring cost of the final rule.

4. Summary of Costs and Benefits

Table 4 of this document shows the median estimated benefits and costs of the final rule.

TABLE 4.—MEDIAN ANNUAL ESTIMATED BENEFITS AND COSTS OF THE FINAL RULE (IN MILLIONS OF DOLLARS)

Benefits/Costs	First Year	All Other Years
Median estimated benefits (USDA[1] SE[2] risk assessment baseline)	$700	$700
Median estimated benefits (original CDC[3] surveillance baseline)	$300	$300
Median estimated benefits (revised CDC surveillance baseline, final rule)	$260	$260
Median estimated costs (proposed rule)	$60	$10

TABLE 4.—MEDIAN ANNUAL ESTIMATED BENEFITS AND COSTS OF THE FINAL RULE (IN MILLIONS OF DOLLARS)—Continued

Benefits/Costs	First Year	All Other Years
Median estimated cost (final rule)	$56	$10

[1] U.S. Department of Agriculture
[2] *Salmonella* Enteritidis
[3] Centers for Disease Control and Prevention

B. Small Entity Analysis

1. Introduction

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that, under the Regulatory Flexibility Act, this final rule will have a significant economic impact on a substantial number of small entities.

2. Economic Effects on Small Entities

a. *Number of small entities affected.* The final rule will affect many small entities, including egg processors, grocery stores and other stores including roadside stands, restaurants, and other food service establishments. FDA has not been able to determine how many of the 669 egg processors registered with the USDA are small businesses (Ref. 11). Egg processors generally fall into two industrial classifications: Poultry slaughtering and processing (standard industrial classification (SIC) code 2015) and whole poultry and poultry products (SIC code 5144). The two classifications roughly correspond to in-line and off-line processors. In-line processors package the eggs at the egg laying facility. Off-line processors ship the eggs to packers.

The Small Business Administration (SBA) defines in-line egg processors (SIC code 2015–03) to be small businesses if they employ 500 or fewer people. According to a search in Dun's Market Identifiers (Ref. 12) 25 in-line egg-processing firms would be defined as small. SBA defines off-line processors (SIC code 5144) to be small if they employ 100 or fewer people. Dun's Market

Identifiers did not have a subcategory for egg processors. For the entire category of poultry and poultry products (SIC code 5144), 80 percent of establishments employ fewer than 100 workers. If the same proportion holds for the subcategory composed of egg processors, then 470 firms would be classified as small.[3] FDA, therefore, estimated the total number of small egg processors to be 495 (= 25 + 470).

The refrigeration provision will affect small establishments that are not currently refrigerating at 7.2 °C (45 °F). SBA defines grocery stores (SIC code 5411) to be small if annual gross revenue is less than $20 million. Other food stores (SIC codes 5431, 5451, and 5499), which include fruit and vegetable markets, dairy product stores, and miscellaneous food stores, are small if annual sales are less than $5 million. Restaurants are small if annual sales are less than $5 million and institutions are small if sales are less than $15 million.

As shown in table 5 of this document, FDA estimated that the number of small establishments affected by the final refrigeration provision will be 25,400. One comment questioned how FDA derived this estimate. The agency derived this estimate of small businesses affected from the estimate for all establishments affected. FDA estimated the number of establishments (small and large) currently not keeping eggs at an ambient temperature of 7.2 °C (45 °F) by assuming that some fraction of establishments in States without temperature requirements were holding eggs at temperatures greater than 7.2 °C (45 °F). FDA does not know the fraction of establishments holding shell eggs at temperatures greater than 7.2 °C (45 °F), so the agency used a Monte Carlo simulation to estimate a distribution for the number of establishments affected. In the simulation, FDA assumed that in each State without a 7.2 °C (45 °F) requirement, between 0 and 100 percent (with 33 percent the most likely proportion) of the establishments held shell eggs at a higher temperature. The mean result of the 1,000 iterations of the simulation was a total of approximately 44,400

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[3] The estimated total number of in-line establishments is 134, but 52 are branches of firms. If the total number of in-line firms is 82(=134 - 52), and the number of processors is 669, then 587 firms are off-line processors. If 80 percent are small, then 470 off-line(=0.8 x 587) processors are small.

large and small establishments, which included 10,700 grocery and other food stores, 24,000 restaurants, and 9,700 institutions (including schools, hospitals, nursing homes, prisons, military establishments, and universities) (64 FR 36516 at 36536, July, 9 1999). FDA reported only the mean of the distribution of simulation results. The results for the simulated number of establishments ranged from a 5th percentile of 12,320 to a 95th percentile of 81,700.

To estimate the number of small establishments holding eggs at temperatures above 7.2 °C (45 °F), FDA assumed that the proportion of small establishments affected by the refrigeration provision would be the same as the fraction of institutions for the entire category. According to SBA size standards for small entities, 71 percent of grocery and other food stores and 54 percent of restaurants are small. Institutions are more complicated, because they cut across SIC codes. FDA assumed that 50 percent of institutions serving eggs are small. FDA then estimated the number of small establishments affected by the refrigeration provision by multiplying the fraction assumed to be small by the total number of establishments affected. Table 5 of this document shows the mean number of small establishments likely to be affected by the refrigeration provision of the final rule. The agency also has included the 5th and 95th percentiles to show the uncertainty associated with the mean estimates. FDA emphasizes that these are estimates, not a count of the actual firms affected. The agency uses them to demonstrate that this final rule will affect a substantial number of small establishments.

TABLE 5.—NUMBER OF SMALL ENTITIES LIKELY TO BE AFFECTED BY THE REFRIGERATION PROVISION OF THE FINAL RULE (SIMULATION RESULTS; ROUNDED TO NEAREST 100)

Category	5th Percentile	Mean	95th Percentile
Grocery and Other Stores	2,100	7,600	14,000
Restaurants	3,600	13,000	23,900
Institutions	1,300	4,800	8,900
Total	7,000	25,400	46,800

b. *Costs for small entities.* For the 9-month compliance period in the final rule, redesign costs per SKU will be about $875 for pulp cartons and $375 for foam cartons.[4] The cost of the labeling

[4] In the analysis of the proposal, FDA estimated that the average redesign cost for foam cartons would be $500 for a 6-month compliance period and $250 for a 12-month compliance period. In the analysis of the final

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provision borne by small processors will vary with the number of SKU's and the fraction of the costs passed to the processors from carton manufacturers. The average number of SKU's per processor for the industry is 30; FDA assumed small processors will market somewhere between 2 and 20 SKU's. Additional redesign costs could, therefore, be as high as $17,500 for a small processor (= 20 x $875), although it is unlikely that the processor would bear all redesign costs.

Refrigeration costs vary across establishments, depending on the age of current refrigerators, the planned replacement cycle, and whether the small establishments are currently keeping eggs at or below 7.2 °C (45 °F). FDA assumed that additional refrigeration costs for small retailers will average $633, with $700 the most likely value. The agency also assumed that the proportion of additional refrigeration costs borne by small entities will be the same as the proportion of small entities in each category of establishment. The cost of the refrigeration provision to small entities is shown in table 6.

TABLE 6.—COSTS TO SMALL ENTITIES OF THE REFRIGERATION PROVISION OF THE FINAL RULE

Category	Total Costs for Small Entities	Percent of Total
Grocery and Other Stores	$4.8 million	30
Restaurants	$8.2 million	51
Institutions	$3.1 million	19
Total	$16.1 million	100

3. Regulatory Options

a. *Exemption for small establishments.* The burden on small establishments would be lifted if they were exempt from the provisions of the final rule. Most of the establishments affected by this final rule, however, are small. Exempting small establishments from its provisions would largely negate the rule. No comments requested exemptions from the proposed rule for small establishments.

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rule, FDA assumed that the redesign cost for a 9-month compliance period will by $375, midway between the two. Similarly, the agency assumed that the redesign costs for a pulp carton will be $875 for a 9-month compliance period, midway between the $1,000 and $750 estimated for 6-month and 12-month compliance periods.

b. *Longer compliance periods*. Lengthening the labeling compliance periods for the labeling and refrigeration provisions would provide regulatory relief (cost reduction) for small entities. Lengthening the refrigeration compliance period from the final rule's effective date to 12 months after the effective date would reduce costs by allowing establishments to postpone upgrading their equipment. To estimate the regulatory relief from lengthening the refrigeration compliance period, FDA assumed that the reduction in cost would equal the interest (discounted at 7 percent per year) on the cost of refrigeration equipment over the extension of the compliance period. If the compliance period were extended by 12 months, the interest on the cost of equipment would be over $1 million (= $16.1 x 0.07). For the most likely equipment cost of $700 per small establishment, the interest saving would be about $50 (= 0.07 x $700). FDA received no comments requesting longer compliance periods for the refrigeration provision.

(Comment 41) Some comments requested a 12-month compliance period for the labeling provision. The agency has responded by increasing the compliance period to 9 months. In the cost analysis of this final rule, FDA estimated that total industry costs would fall by at least $3 million if the compliance period for the labeling provisions were extended from 6 months to 9 months. Most of the relief will come from the reduced costs of redesigning the carton label and reduced inventory disposal costs. For pulp cartons, extending the compliance period to 9 months will reduce redesign costs from $1,000 (for a 6-month compliance period) to $875 per SKU. For foam cartons, extending the compliance period to 9 months will reduce redesign costs from $500 (for a 6-month compliance period) to $375 per SKU. The comments stressed the difficulty of redesign caused by the length of the statement in the proposal. Because the safe handling statement in the final rule has been shortened, FDA expects that redesign costs will not be as large a burden as many comments on the proposed rule implied. Furthermore, redesign costs are not necessarily passed on to small processors.

Small processors will, however, bear inventory disposal costs. In the cost analysis of the proposal, FDA estimated disposal costs for label inventories to be $3 million for a 6-month

compliance period. The agency believes that the principal relief for small egg packers and processors will come from the reduction in inventory costs. For a 9-month compliance period, the disposal costs for label inventories will be $2,250,000. FDA does not know what fraction of those costs will be borne by small processors. If the agency assumes that small processors bear half of the disposal costs, then the average inventory cost per small processor would be $3,000 (= ($3,000,000 x 0.5) / 495) for a 6-month compliance period and $2,250 (= ($2,250,000 x 0.5) / 495) for a 9-month compliance period. Changing the effective date to 9 months after publication will, therefore, save $750 per small processor. For processors holding large inventories, the saving will be larger. The longer compliance period will also increase the likelihood that small processors will use up their carton inventories and bear no disposal costs.

4. Recordkeeping and Recording Requirements

The Regulatory Flexibility Act requires a description of the recordkeeping and recording required for compliance with this rule. This rule does not require the preparation of a report or a record.

5. Worst Case for a Small Establishment

The greatest impact to a small retail establishment as a consequence of the refrigeration provision would be the purchase of a new refrigerator. In the analysis of the proposal, FDA estimated the cost of a new refrigerator to be between $2,500 and $6,000. In order to estimate the worst possible outcome for a small entity, FDA assumed that some small retail establishment would purchase a new refrigerator at the maximum estimated cost of $6,000. If this cost were amortized over a 10-year period (using a discount rate of 7 percent) then the approximate annual expense would be $850 per year for 10 years. According to Dun and Bradstreet, 85 percent of all grocery stores have annual sales of less than $20 million, and 71 percent of all restaurants have annual sales of less than $5 million (Ref. 12). Among the smallest 10 percent of these establishments, the average sales volume is $100,000 per year for a grocery store and $50,000

per year for a restaurant. Therefore, an additional expense of $850 per year amounts to approximately 1 to 2 percent of average sales per year for the smallest stores. Grocery stores and restaurants typically have profit margins on sales of 1 to 5 percent, so a reduction of the profit margin by 40 to 100 percent would be the worst-case outcome for the smallest retailers.

Because the comments on the proposed rule emphasized the importance of inventories, FDA concludes that the worst outcome from the labeling provision would occur if a small packer held large inventories of cartons that could not be used. If average inventory costs per small processor (for a 9-month compliance period) are $2,250, some establishments could bear much higher inventory costs.

6. Summary of Small Entity Analysis

FDA estimated that the labeling provisions could impose average inventory costs of $2,250 on 495 small processing establishments. The refrigeration provision would impose estimated average costs of $633 on approximately 25,400 small establishments. The agency concludes that this final rule will have a significant economic impact on a substantial number of small entities.

V. Federalism

These rules establish national safe handling labeling and retail refrigeration requirements for shell eggs under the FD&C Act and the PHS Act. FDA has determined that these egg safety final rules have federalism implications under Executive Order 13132 because they will preempt State and local labeling and retail refrigeration requirements that are not as stringent as Federal requirements. Although FDA proposed this rule before Executive Order 13132 was issued or became effective, FDA believes that these final rules satisfy the requirements of Executive Order 13132.

The constitutional basis for FDA's authority to regulate the safety and labeling of foods is the statutes created by Congress to regulate food safety. As set out in the preamble to the proposed and final rules, foodborne illness resulting from SE contaminated eggs is a public health problem

nationwide. However, only 37 States and the District of Columbia require refrigeration at 7.2 °C (45 °F) or lower in retail establishments, the temperature that FDA has determined is necessary to prevent growth of SE. No State has a requirement for complete safe handling instructions. Accordingly, there is a clear need for Federal action to establish national standards that will ensure the safety of eggs for all consumers in this country.

To ensure the safety of eggs for all consumers in this country, not only must there be national standards, but enforcement of these standards must be uniform across the country. However, because State and local public health officials are the primary enforcement officials in retail establishments, FDA has recognized that it must rely on these officials to provide the bulk of the enforcement of these regulations. FDA thus believes that it is critical for these regulations to establish uniform minimum standards. If less stringent State or local refrigeration and labeling requirements are not preempted, enforcement of those less stringent requirements—which are not sufficient to protect the public health—will interfere with the cooperative enforcement of the Federal egg refrigeration and labeling requirements. FDA believes that the cooperative enforcement approach utilized in these rules is critical to effective implementation of these important food safety requirements.

Thus, although Congress did not expressly preempt State law in this area, FDA finds preemption is needed because State and local laws that are less stringent than the Federal requirements will significantly interfere with the important public health goals of these regulations.

FDA does not believe that preemption of State and local refrigeration and labeling requirements that are the same as or more stringent than the requirements of these regulations is necessary, as enforcement of such State and local requirements will not interfere with the food safety goals of these regulations. Accordingly, the preemptive effect of this rule is limited to State or local requirements that are not as stringent as the requirements of these regulations; requirements that are the same as or more stringent than FDA's requirements remain in effect.

Although the proposed rule was published before Executive Order 13132, FDA gave States and localities notice of the intended preemptive effect of these rules in the notice of proposed rulemaking. In addition, FDA consulted with representatives of State and local governments before issuing the proposal. FDA received one comment from a State Department of Agriculture, which did not discuss preemption and one comment from an organization representing State and local food safety officials, which raised questions about the scope of preemption. These questions are answered in the body of the preamble. As set out in the preamble and this discussion on federalism, the preemptive effect of these regulations is very narrow.

VI. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposal (64 FR 36492, July 6, 1999). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that environmental impact statement is not required.

VII. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the safe handling statement is ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VIII. References

The following references have been placed on display at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. President's Council on Food Safety, ''Egg Safety from Production to Consumption: an Action Plan to Eliminate *Salmonella* Enteritidis Illnesses due to Eggs,'' December 10, 1999.

2. Summary Report on Focus Group Testing of Safe Handling Statements on Shell Eggs. Levy, A. S. and A. W. Heaton, Consumer Studies Team, Office of Scientific Analysis and Support, Center for Food Safety and Applied Nutrition, Food and Drug Administration, March 13, 1998.

3. FDA memorandum, Alan S. Levy to Kenneth Falci, June 26, 1999.

4. ''FDA: Consumers are Changing,'' *Food Safety Educator*, vol. 3(4), p. 2, 1998.

5. U.S. Public Health Service, ''Food Code: 1999, Recommendations of the United States Public Health Service, Food and Drug Administration,'' Ch. 3.

6. Review of Research Communicating Warning Information. Consumer Studies Team, Office of Scientific Analysis and Support, Center for Food Safety and Applied Nutrition, Food and Drug Administration, p. 54, July 1998.

7. Food Marketing Institute (conducted by Abt Associates, Inc.), ''Trends in the United States: Consumer Attitudes & the Supermarket,'' Washington, DC, Food Marketing Institute, 1996.

8. United States Department of Agriculture, Food Safety and Inspection Service, FSIS Directive 8840.1, ''Enforcement of Refrigeration and Labeling Requirements for Shell Eggs Packed for Consumer Use,'' June 18, 1999.

9. Centers for Disease Control and Prevention, ''Incidence of Foodborne Illnesses: Preliminary Data from the Foodborne Diseases Active Surveillance Network (FoodNet)—United States, 1998,'' *Morbidity and Mortality Weekly Report*, vol. 48, pp. 189–194, March 12, 1999.

10. Mead, P. S., L. Slutsker, V. Dietz, L. F. McCaig, J. S. Bresee, C. Shapiro, P. M. Griffin, and R. V. Tauxe, ''Food-Related Illness and Death in the United States,'' *Emerging Infectious Diseases*, vol. 5, pp. 607–625, September to October 1999.

11. FDA memorandum, Peter Vardon to the record, October 7, 1998.

12. The Dialog Corp., Dun's Market Identifiers, Mountain View, CA, March 19, 1998.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 115

Eggs, Refrigeration.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Services Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

2. Section 16.5 is amended by adding paragraph (a)(4) to read as follows:

§ 16.5 Inapplicability and limited applicability.

(a) * * *

(4) A hearing on an order for relabeling, diversion, or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264) and §§ 101.17(h) and 115.50 of this chapter.

* * * * *

PART 101—FOOD LABELING

3. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

4. Section 101.17 is amended by revising the section heading and by adding paragraph (h) to read as follows:

§ 101.17 Food labeling warning, notice, and safe handling statements.

* * * * *

(h) *Shell eggs.* (1) The label of all shell eggs, whether in intrastate or interstate commerce, shall bear the following statement:

SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.

(2) The label statement required by paragraph (h)(1) of this section shall appear prominently and conspicuously, with the words ''SAFE HANDLING INSTRUCTIONS'' in bold type, on the information panel or principal display panel of the container.

(3) The label statement required by paragraph (h)(1) of this section shall be set off in a box by use of hairlines.

(4) Shell eggs that have been, before distribution to consumers, specifically processed to destroy all viable *Salmonella* shall be exempt from the requirements of paragraph (h) of this section.

(5) The safe handling statement for shell eggs that are not for direct sale to consumers, e.g., those that are to be repacked or labeled at a site other than where originally processed, or are sold for use in food service establishments, may be provided on cartons or in labeling, e.g., invoices or bills of lading in accordance with the practice of the trade.

(6) Under sections 311 and 361 of the Public Health Service Act (PHS Act), any State or locality that is willing and able to assist the agency in the enforcement of paragraphs (h)(1) through (h)(5) of this section, and is authorized to inspect or regulate establishments handling packed shell eggs, may in its own jurisdiction, enforce paragraphs (h)(1) through (h)(5) of this section through

inspections under paragraph (h)(8) of this section and through administrative enforcement remedies identified in paragraph (h)(7) of this section until FDA notifies the State or locality in writing that such assistance is no longer needed. When providing such assistance, a State or locality may follow the hearing procedures set out in paragraphs (h)(7)(ii)(C) through (h)(7)(ii)(D) of this section, substituting, where necessary, appropriate State or local officials for designated FDA officials or may utilize State or local hearing procedures if such procedures satisfy due process.

(7) This paragraph (h) is established under authority of both the Federal Food, Drug, and Cosmetic Act (the act) and the PHS Act. Under the act, the agency can enforce the food misbranding provisions under 21 U.S.C. 331, 332, 333, and 334. However, 42 U.S.C. 264 provides for the issuance of implementing enforcement regulations; therefore, FDA has established the following administrative enforcement procedures for the relabeling, diversion, or destruction of shell eggs and informal hearings under the PHS Act:

(i) Upon finding that any shell eggs are in violation of this section an authorized FDA representative or State or local representative in accordance with paragraph (h)(6) of this section may order such eggs to be relabeled under the supervision of said representative, diverted, under the supervision of said representative for processing in accordance with the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*), or destroyed by or under the supervision of an officer or employee of the FDA, or, if applicable, of the State or locality, in accordance with the following procedures:

(A) *Order for relabeling, diversion, or destruction under the PHS Act.* Any district office of the FDA or any State or locality acting under paragraph (h)(6) of this section, upon finding shell eggs held in violation of this regulation, may serve upon the person in whose possession such eggs are found a written order that such eggs be relabeled with the required statement in paragraph (h)(1) of this section before further distribution. If the person chooses not to relabel, the district office of the FDA or, if applicable, the appropriate State or local agency may serve upon the person a written order that such eggs be diverted (from direct consumer sale, e.g., to

food service) under the supervision of an officer or employee of the issuing entity, for processing in accordance with the EPIA (21 U.S.C. 1031 *et seq.*) or destroyed by or under the supervision of the issuing entity, within 10-working days from the date of receipt of the order.

(B) *Issuance of order.* The order shall include the following information:

(*1*) A statement that the shell eggs identified in the order are subject to relabeling, diversion for processing in accordance with the EPIA, or destruction;

(*2*) A detailed description of the facts that justify the issuance of the order;

(*3*) The location of the eggs;

(*4*) A statement that these eggs shall not be sold, distributed, or otherwise disposed of or moved except as provided in paragraph (h)(7)(i)(E) of this section;

(*5*) Identification or description of the eggs;

(*6*) The order number;

(*7*) The date of the order;

(*8*) The text of this entire section;

(*9*) A statement that the order may be appealed by written appeal or by requesting an informal hearing;

(*10*) The name and phone number of the person issuing the order; and

(*11*) The location and telephone number of the responsible office or agency and the name of its director.

(C) *Approval of director.* An order, before issuance, shall be approved by the director of the office or agency issuing the order. If prior written approval is not feasible, prior oral approval shall be obtained and confirmed by written memorandum as soon as possible.

(D) *Labeling or marking of shell eggs under order.* An FDA, State, or local representative issuing an order under paragraph (h)(7)(i)(A) of this section shall label or mark the shell eggs with official tags that include the following information:

(*1*) A statement that the shell eggs are detained in accordance with regulations issued under section 361(a) of the PHS Act (42 U.S.C. 264(a)).

(2) A statement that the shell eggs shall not be sold, distributed or otherwise disposed of or moved except, after notifying the issuing entity in writing, to:

(*i*) Relabel, divert them for processing in accordance with the EPIA, or destroy them, or

(*ii*) Move them to another location for holding pending appeal.

(3) A statement that the violation of the order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 368 of the PHS Act, 42 U.S.C. 271).

(4) The order number and the date of the order, and the name of the government representative who issued the order.

(E) *Sale or other disposition of shell eggs under order.* After service of the order, the person in possession of the shell eggs that are the subject of the order shall not sell, distribute, or otherwise dispose of or move any eggs subject to the order unless and until the notice is withdrawn after an appeal except, after notifying FDA's district office or, if applicable, the State or local agency in writing, to:

(1) Relabel, divert, or destroy them as specified in paragraph (h)(7)(i) of this section, or

(2) Move them to another location for holding pending appeal.

(ii) The person on whom the order for relabeling, diversion, or destruction is served may either comply with the order or appeal the order to the FDA Regional Food and Drug Director.

(A) *Appeal of a detention order.* Any appeal shall be submitted in writing to the FDA District Director in whose district the shell eggs are located within 5-working days of the issuance of the order. If the appeal includes a request for an informal hearing, the hearing shall be held within 5-working days after the appeal is filed or, if requested by the appellant, at a later date, which shall not be later than 20-calendar days after the issuance of the order. The order may also be appealed within the same period of 5-working days by any other person having an ownership or proprietary interest in such shell eggs. The appellant of an order shall state the ownership or proprietary interest the appellant has in the shell eggs.

(B) *Summary decision.* A request for a hearing may be denied, in whole or in part and at any time after a request for a hearing has been submitted, if the FDA Regional Food and Drug

Director or his or her designee determines that no genuine and substantial issue of fact has been raised by the material submitted in connection with the hearing or from matters officially noticed. If the FDA Regional Food and Drug Director determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(C) *Informal hearing*. Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The informal hearing shall be conducted by the FDA Regional Food and Drug Director or his designee, and a written summary of the proceedings shall be prepared by the FDA Regional Food and Drug Director.

(*1*) The FDA Regional Food and Drug Director may direct that the hearing be conducted in any suitable manner permitted by law and this section. The FDA Regional Food and Drug Director has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct an informal fair, expeditious, and impartial hearing, and to enforce the requirements concerning the conduct of hearings.

(*2*) Employees of FDA will first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present oral or written information relevant to the hearing. The party requesting the hearing may then present oral or written information relevant to the hearing. All parties may conduct reasonable examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(*3*) The hearing shall be informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any party may comment upon or rebut any information and views presented by another party.

(*4*) The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the FDA Regional Food and Drug Director's report of the hearing.

(5) The FDA Regional Food and Drug Director shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the FDA Regional Food and Drug Director may give the parties the opportunity to review and comment on the report of the hearing.

(6) The FDA Regional Food and Drug Director shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons.

(D) *Written appeal.* If the appellant appeals the detention order but does not request a hearing, the FDA Regional Food and Drug Director shall render a decision on the appeal affirming or revoking the detention within 5-working days after the receipt of the appeal.

(E) *Regional Food and Drug Director decision.* If, based on the evidence presented at the hearing or by the appellant in a written appeal, the FDA Regional Food and Drug Director finds that the shell eggs were held in violation of this section, he shall affirm the order that they be relabeled, diverted under the supervision of an officer or employee of the FDA for processing under the EPIA, or destroyed by or under the supervision of an officer or employee of the FDA; otherwise, the FDA Regional Food and Drug Director shall issue a written notice that the prior order is withdrawn. If the FDA Regional Food and Drug Director affirms the order he shall order that the relabeling, diversion, or destruction be accomplished within 10-working days from the date of the issuance of his decision. The FDA Regional Food and Drug Director's decision shall be accompanied by a statement of the reasons for the decision. The decision of the FDA Regional Food and Drug Director shall constitute final agency action, reviewable in the courts.

(F) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to relabel, divert, or destroy them within 10-working days, or if the demand is affirmed by the FDA Regional Food and Drug Director after an appeal and the person in possession of such eggs fails to relabel, divert, or destroy them within 10-working days, the FDA district office, or, if applicable, the State or local agency may designate an officer

or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

(8) Persons engaged in handling or storing packed shell eggs for retail distribution shall permit authorized representatives of FDA to make at any reasonable time such inspection of the establishment in which shell eggs are being held, including inspection and sampling of the labeling of such eggs as may be necessary in the judgment of such representatives to determine compliance with the provisions of this section. Inspections may be made with or without notice and will ordinarily be made during regular business hours.

(9) No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement requiring safe handling instructions on unpasteurized shell eggs that are less stringent than those required in paragraphs (h)(1) through (h)(5) of this section.

5. New part 115 is added to read as follows:

PART 115—SHELL EGGS

Authority: 21 U.S.C. 342, 371; 42 U.S.C. 243, 264, 271.

§ 115.50 Refrigeration of shell eggs held for retail distribution.

(a) For purposes of this section a ''retail establishment'' is an operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption directly to consumers.

(b) Except as provided in paragraph (c) of this section, all shell eggs, whether in intrastate or interstate commerce, held for retail distribution:

(1) Shall promptly be placed under refrigeration as specified in paragraph (b)(2) of this section upon receipt at a retail establishment, except that, when short delays are unavoidable, the eggs shall be placed under refrigeration, as soon as reasonably possible; and

(2) Shall be stored and displayed under refrigeration at an ambient temperature not greater than 7.2 °C (45 °F) while held at a retail establishment.

(c) Shell eggs that have been specifically processed to destroy all viable *Salmonella* shall be exempt from the requirements of paragraph (b) of this section.

(d) Under sections 311 and 361 of the Public Health Service Act (PHS Act), any State or locality that is willing and able to assist the agency in the enforcement of paragraph (b) of this section, and is authorized to inspect or regulate retail establishments, may, in its own jurisdiction, enforce paragraph (b) of this section through inspections under paragraph (f) of this section and through administrative enforcement remedies identified in paragraph (e) of this section until FDA notifies the State or locality in writing that such assistance is no longer needed. When providing assistance under paragraph (e) of this section, a State or locality may follow the hearing procedures set out in paragraphs (e)(2)(iii) through (e)(2)(iv) of this section, substituting, where necessary, appropriate State or local officials for designated FDA officials or may utilize State or local hearing procedures if such procedures satisfy due process.

(e) This section is established under authority of both the Federal Food, Drug, and Cosmetic Act (the act) and the PHS Act. Under the act, the agency can enforce the food adulteration provisions under 21 U.S.C. 331, 332, 333, and 334. However, 42 U.S.C. 264 provides for the issuance of implementing enforcement regulations; therefore, FDA has established the following administrative enforcement procedures for the diversion or destruction of shell eggs and for informal hearings under the PHS Act:

(1) Upon finding that any shell eggs have been held in violation of this section, an authorized FDA representative or a State or local representative in accordance with paragraph (d) of this section may order such eggs to be diverted, under the supervision of said representative, for processing in accordance with the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*) or destroyed by or under the supervision of an officer or employee of the FDA, or, if applicable, of the State or locality in accordance with the following procedures:

(i) *Order for diversion or destruction.* Any district office of FDA or any State or local agency acting under paragraph (d) of this section, upon finding shell eggs held in violation of this section,

may serve upon the person in whose possession such eggs are found a written order that such eggs be diverted, under the supervision of an officer or employee of the issuing entity, for processing in accordance with the EPIA (21 U.S.C. 1031 *et seq.*) or destroyed by or under the supervision of said district office, within 10-working days from the date of receipt of the order.

(ii) *Issuance of order.* The order shall include the following information:

(A) A statement that the shell eggs identified in the order are subject to diversion for processing in accordance with the EPIA or destruction;

(B) A detailed description of the facts that justify the issuance of the order;

(C) The location of the eggs;

(D) A statement that these eggs shall not be sold, distributed, or otherwise disposed of or moved except as provided in paragraph (e)(1)(v) of this section;

(E) Identification or description of the eggs;

(F) The order number;

(G) The date of the order;

(H) The text of this entire section;

(I) A statement that the order may be appealed by written appeal or by requesting an informal hearing;

(J) The name and phone number of the person issuing the order; and

(K) The location and telephone number of the office or agency and the name of its director.

(iii) *Approval of District Director.* An order, before issuance, shall be approved by the Food and Drug Administration (FDA) District Director in whose district the shell eggs are located. If prior written approval is not feasible, prior oral approval shall be obtained and confirmed by written memorandum as soon as possible.

(iv) *Labeling or marking of shell eggs under order.* An FDA, State, or local agency representative issuing an order under paragraph (e)(1) of this section shall label or mark the shell eggs with official tags that include the following information:

(A) A statement that the shell eggs are detained in accordance with regulations issued under section 361(a) of the PHS Act (42 U.S.C. 264(a)).

(B) A statement that the shell eggs shall not be sold, distributed or otherwise disposed of or moved except, after notifying the issuing entity in writing, to:

(*1*) Divert them for processing in accordance with the EPIA or destroy them; or

(2) Move them to an another location for holding pending appeal.

(C) A statement that the violation of the order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 368 of the PHS Act, 42 U.S.C. 271).

(D) The order number and the date of the order, and the name of the government representative who issued the order.

(v) *Sale or other disposition of shell eggs under order.* After service of the order, the person in possession of the shell eggs that are the subject of the order shall not sell, distribute, or otherwise dispose of or move any eggs subject to the order unless and until the notice is withdrawn after an appeal except, after notifying FDA's district office or, if applicable, the State or local agency in writing, to:

(A) Divert or destroy them as specified in paragraph (e)(1)(i) of this section; or

(B) Move them to another location for holding pending appeal.

(2) The person on whom the order for diversion or destruction is served may either comply with the order or appeal the order to the FDA Regional Food and Drug Director in accordance with the following procedures:

(i) *Appeal of a detention order.* Any appeal shall be submitted in writing to FDA's District Director in whose district the shell eggs are located within 5-working days of the issuance of the order. If the appeal includes a request for an informal hearing, the hearing shall be held within 5-working days after the appeal is filed or, if requested by the appellant, at a later date, which shall not be later than 20-calendar days after the issuance of the order. The order may also be appealed within the same period of 5-working days by any other person having an ownership

or proprietary interest in such shell eggs. The appellant of an order shall state the ownership or proprietary interest the appellant has in the shell eggs.

(ii) *Summary decision.* A request for a hearing may be denied, in whole or in part and at any time after a request for a hearing has been submitted, if the FDA Regional Food and Drug Director or his or her designee determines that no genuine and substantial issue of fact has been raised by the material submitted in connection with the hearing or from matters officially noticed. If the FDA Regional Food and Drug Director determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(iii) *Informal hearing.* Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The informal hearing shall be conducted by the FDA Regional Food and Drug Director or his designee, and a written summary of the proceedings shall be prepared by the FDA Regional Food and Drug Director.

(A) The FDA Regional Food and Drug Director may direct that the hearing be conducted in any suitable manner permitted by law and this section. The FDA Regional Food and Drug Director has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct an informal fair, expeditious, and impartial hearing, and to enforce the requirements concerning the conduct of hearings.

(B) Employees of FDA will first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present oral or written information relevant to the hearing. The party requesting the hearing may then present oral or written information relevant to the hearing. All parties may conduct reasonable examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(C) The hearing shall be informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any party may comment upon or rebut any information and views presented by another party.

(D) The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the FDA Regional Food and Drug Director's report of the hearing.

(E) The FDA Regional Food and Drug Director shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the FDA Regional Food and Drug Director may give the parties the opportunity to review and comment on the report of the hearing.

(F) The FDA Regional Food and Drug Director shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons.

(iv) *Written appeal.* If the appellant appeals the detention order but does not request a hearing, the FDA Regional Food and Drug Director shall render a decision on the appeal affirming or revoking the detention within 5-working days after the receipt of the appeal.

(v) *Regional Food and Drug Director decision.* If, based on the evidence presented at the hearing or by the appellant in a written appeal, the Regional Food and Drug Director finds that the shell eggs were held in violation of this section, he shall affirm the order that they be diverted, under the supervision of an officer or employee of the FDA for processing under the EPIA or destroyed by or under the supervision of an officer or employee of the FDA; otherwise, the Regional Food and Drug Director shall issue a written notice that the prior order is withdrawn. If the Regional Food and Drug Director affirms the order he shall order that the diversion or destruction be accomplished within 10-working days from the date of the issuance of his decision. The Regional Food and Drug Director's decision shall be accompanied by a statement of the reasons for the decision. The decision of the Regional Food and Drug Director shall constitute final agency action, reviewable in the courts.

(vi) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to divert or destroy them within 10-working days, or if

the demand is affirmed by the Regional Food and Drug Director after an appeal and the person in possession of such eggs fails to divert or destroy them within 10-working days, FDA's district office or appropriate State or local agency may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

(f) *Inspection.* Persons engaged in retail distribution of shell eggs shall permit authorized representatives of FDA to make at any reasonable time such inspection of the retail establishment in which shell eggs are being held, including inspection and sampling of such eggs and the equipment in which shell eggs are held and any records relating to such equipment or eggs, as may be necessary in the judgement of such representatives to determine compliance with the provisions of this section. Inspections may be made with or without notice and will ordinarily be made during regular business hours.

(g) *Preemption.* No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement allowing refrigeration of unpasteurized shell eggs at retail establishments at any temperature greater than 7.2 °C (45 °F).

Dated: JUN 2 2000

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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